Health Canada Santé Canada

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Brand Name/Active Ingredient: covid
Search Date Criteria: 2021-01-01 to 2021-04-30
Reaction Term(s): All/Tous
Serious report?: Both
Type of Report: All
Source of Report: All
Gender: All
Report Outcome: All
Age: All

CAVEAT: This summary is based on information from adverse reaction reports submitted by health professionals and laypersons either directly to Health Canada or via market authorization holders. Each report represents the suspicion, opinion or observation of the individual reporter. The Canada Vigilance Program is a spontaneous reporting system that is suitable to detect signals of potential health product safety issues during the post-market period. The data has been collected primarily by a spontaneous surveillance system in which adverse reactions to health products are reported on a voluntary basis. Under reporting of adverse reactions is seen with both voluntary and mandatory spontaneous surveillance systems. Accumulated case reports should not be used as a basis for determining the incidence of a reaction or estimating risk for a particular product as neither the total number of reactions occurring, nor the number of patients exposed to the health product is known. Because of the multiple factors that influence reporting, quantitative comparisons of health product safety cannot be made from the data. Some of these factors include the length of time a drug is marketed, the market share, size and sophistication of the sales force, publicity about an adverse reaction and regulatory actions. In some cases, the reported clinical data is incomplete and there is not certainty that these health products caused the reported reactions. A given reaction may be due to an underlying disease process or to another coincidental factor. This information is provided with the understanding that the data will be appropriately referenced and used in conjunction with this caveat statement.

Canada

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Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000935310	0	2021-01-07	2021-01-07	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Parenteral				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Contusion	v.24.1	
Eye pain	v.24.1	
Eye swelling	v.24.1	4 Days
Injection site nodule	v.24.1	

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Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000935926	0	2021-01-14	2021-01-14	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
51 Years	Female	159 Centimeter	62 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CRESTOR	Concomitant	Tablets					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		COVID-19 prophylaxis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.24.1	1 Days
Hypotension	v.24.1	1 Days
Injection site pain	v.24.1	1 Days
Vomiting	v.24.1	1 Days

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Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000936018	0	2021-01-15	2021-01-15	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
59 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cellulitis	v.24.1	
Induration	v.24.1	
Injection site erythema	v.24.1	
Injection site pain	v.24.1	
Injection site warmth	v.24.1	

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Report Information

***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000936055	1	2021-01-16	2021-01-16	Hospital		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
51 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR		0.3 ml	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Lip oedema	v.24.1	
Pharyngeal oedema	v.24.1	
Rash	v.24.1	
Tongue oedema	v.24.1	

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Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000936056	0	2021-01-15	2021-01-15	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
47 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MULTIVITAMINS WITH MINERALS	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				COVID-19 immunisation
PROPRANOLOL	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Conjunctival haemorrhage	v.24.1	
Headache	v.24.1	
Ocular discomfort	v.24.1	

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Report Information ***AER = Adverse Reaction Report*

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000936058	0	2021-01-16	2021-01-16	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
41 Years	Female		68 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Swelling	v.24.1	

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000936126	0	2021-01-18	2021-01-18	Community		Spontaneous	Nurse

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.24.1	
Feeling cold	v.24.1	
Feeling hot	v.24.1	
Hyperhidrosis	v.24.1	
Tremor	v.24.1	

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000936347	0	2021-01-20	2021-01-20	Hospital		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
46 Years	Female			Recovered/resolved with sequelae

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Flushing	v.24.1	
Headache	v.24.1	
Paraesthesia oral	v.24.1	
Pruritus	v.24.1	
Rash	v.24.1	

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000936378	0	2021-01-20	2021-01-20	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
23 Years	Female	170 Centimeter	77 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
IBUPROFEN	Concomitant	Tablets					
KETOROLAC	Concomitant	Tablets					
MAXALT	Concomitant	Tablets	Unknown				
METOCLOPRAMIDE	Concomitant	NOT SPECIFIED					
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SUSPENSION INTRAMUSCULAR		5.0 Milligram	1 every 4 Weeks		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Balance disorder	v.24.1	
Chills	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Decreased appetite	v.24.1	
Dizziness	v.24.1	
Migraine	v.24.1	
Nausea	v.24.1	
Pyrexia	v.24.1	
Vomiting	v.24.1	

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000936467	0	2021-01-21	2021-01-21	Community		Spontaneous	Physician

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male	171 Centimeter	88 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR					COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.24.1	
Urticaria	v.24.1	

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Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000936546	0	2021-01-21	2021-01-21	Hospital		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
36 Years	Female	170 Centimeter	79 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
EMGALITY 100MG	Concomitant	NOT SPECIFIED	Unknown				
MELATONIN	Concomitant	NOT SPECIFIED					
NORLUTATE	Concomitant	Tablets					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		1 every 21 Days	21.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Lymph node pain	v.24.1	
Lymphadenopathy	v.24.1	

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000936911	0	2021-01-25	2021-01-25	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female	181 Centimeter	64 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ELTROXIN	Concomitant	Tablets					
IRON	Concomitant	NOT SPECIFIED					
MAGNESIUM GLYCINATE	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	1.0 Dosage forms	Once		COVID-19 prophylaxis
VITAMIN C	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Lymphadenopathy	v.24.1	12 Days

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Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000937271	0	2021-01-27	2021-01-27	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
37 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR			Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Erythema	v.24.1	
Hypersensitivity	v.24.1	
Palmar erythema	v.24.1	
Pruritus	v.24.1	

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Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000937282	0	2021-01-27	2021-01-27	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
77 Years	Female		91 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETAMINOPHEN	Concomitant	NOT SPECIFIED					
ATORVASTATIN	Concomitant	Tablets					
BETADERM CRM 0.1%	Concomitant	Cream					
BUPROPION XL	Concomitant	TABLET (EXTENDED-RELEASE)	Unknown				
CALCIUM	Concomitant	NOT SPECIFIED					
CHLORHEXIDINE	Concomitant	MOUTHWASH					
CHOLECALCIFEROL	Concomitant	NOT SPECIFIED					
EPINEPHRINE	Concomitant	NOT SPECIFIED					
EURO-K20 TABLET (SUSTAINED RELEASE)	Concomitant	TABLET (EXTENDED-RELEASE)					
EZETIMIBE	Concomitant	Tablets					
FERROUS FUMARATE	Concomitant	NOT SPECIFIED					
GABAPENTIN	Concomitant	NOT SPECIFIED					

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
HYDROMORPH CONTIN	Concomitant	CAPSULE, SUSTAINED-RELEASE					
HYDROMORPHONE	Concomitant	NOT SPECIFIED					
INDERAL LA	Concomitant	CAPSULE, SUSTAINED-RELEASE					
LACTULOSE SYRUP	Concomitant	NOT SPECIFIED					
LATUDA	Concomitant	Tablets					
LITHIUM CARBONATE	Concomitant	NOT SPECIFIED					
MELATONIN	Concomitant	NOT SPECIFIED					
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SUSPENSION INTRAMUSCULAR			Once		
MYRBETRIQ	Concomitant	TABLET (EXTENDED-RELEASE)					
OTRIVIN	Concomitant	NOT SPECIFIED					
PANTOPRAZOLE	Concomitant	NOT SPECIFIED					
PROLIA	Concomitant	SOLUTION SUBCUTANEOUS					
SENNOSIDES A+B SANDOZ	Concomitant	NOT SPECIFIED					
TRAZODONE	Concomitant	Tablets					
VITAMIN B12	Concomitant	NOT SPECIFIED					
VOLTAREN EMULGEL BACK & MUSCLE PAIN	Concomitant	GEL					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Discomfort	v.24.1	
Fatigue	v.24.1	
Feeding disorder	v.24.1	
Feeling abnormal	v.24.1	
Gait inability	v.24.1	
Insomnia	v.24.1	
Loss of personal independence in daily activities	v.24.1	
Myoclonic epilepsy	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Tremor	v.24.1	

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000937418	0	2021-01-28	2021-01-28	Community		Spontaneous	Physician

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
40 Years	Female	160 Centimeter	57 Kilogram	Recovering/resolving

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SUSPENSION INTRAMUSCULAR			Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Rash	v.24.1	
Urticaria	v.24.1	

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000937419	0	2021-01-28	2021-01-28	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
32 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Disturbance in attention	v.24.1	4 Days
Dizziness	v.24.1	4 Days
Headache	v.24.1	4 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000937588	0	2021-01-26	2021-01-26	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
36 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	1.0 Dosage forms	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cellulitis	v.24.1	
Injection site warmth	v.24.1	
Rash erythematous	v.24.1	
Rash pruritic	v.24.1	7 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000937589	0	2021-01-29	2021-01-29	Community		Spontaneous	Physician

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
25 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Paraesthesia oral	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000937744	0	2021-02-01	2021-02-01	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
88 Years	Female	150 Centimeter	55 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	1.0 Dosage forms	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Injection site erythema	v.24.1	
Injection site induration	v.24.1	13 Days
Injection site rash	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000937999	0	2021-02-03	2021-02-03	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
42 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR			Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Diarrhoea	v.24.1	
Fatigue	v.24.1	
Hypoaesthesia	v.24.1	
Nausea	v.24.1	
Pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000938000	0	2021-02-03	2021-02-03	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
32 Years	Female	163 Centimeter	90 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	1.0 Dosage forms	1 every 21 Days		Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pityriasis rosea	v.24.1	
Rash	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000938129	0	2021-02-04	2021-02-04	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
74 Years	Female		86 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	1.0 Dosage forms	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Diarrhoea	v.24.1	
Headache	v.24.1	
Nausea	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000938130	0	2021-02-04	2021-02-04	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
36 Years	Female	161 Centimeter	64 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ELTROXIN	Concomitant	Tablets					
IRON	Concomitant	NOT SPECIFIED					
MAGNESIUM GLYCINATE	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	1.0 Dosage forms	Once		COVID-19 prophylaxis
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	1.0 Dosage forms	Once		COVID-19 prophylaxis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Lymph node pain	v.24.1	
Lymphadenopathy	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000938297	0	2021-02-06	2021-02-06	Community		Spontaneous	Physician

Serious report?	Death:		Disability:		Congenital Anomaly:	
Not Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	

Patient Information

Age	Gender	Height	Weight	Report Outcome
61 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR		1.0 Dosage forms	Once		Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.24.1	
Pyrexia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000938438	0	2021-02-08	2021-02-08	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
75 Years	Female		40 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Injection site pruritus	v.24.1	
Injection site rash	v.24.1	
Rash papular	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000938439	0	2021-02-08	2021-02-08	Hospital		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
47 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	1.0 Dosage forms	Once		COVID-19 immunisation
RAMIPRIL	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal discomfort	v.24.1	
Anxiety	v.24.1	
Blood pressure increased	v.24.1	
Dizziness	v.24.1	
Headache	v.24.1	
Nausea	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Paraesthesia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000938440	0	2021-02-08	2021-02-08	Hospital		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	1.0 Dosage forms	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Condition aggravated	v.24.1	
Fatigue	v.24.1	
Insomnia	v.24.1	
Oral mucosal blistering	v.24.1	
Pain in extremity	v.24.1	
Pemphigoid	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pruritus	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000938441	0	2021-02-08	2021-02-08	Hospital		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR			Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.24.1	
Fatigue	v.24.1	
Heart rate increased	v.24.1	
Hypoaesthesia	v.24.1	7 Days
Malaise	v.24.1	
Nausea	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pallor	v.24.1	
Paraesthesia	v.24.1	
Sensory loss	v.24.1	7 Days
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000938442	0	2021-02-08	2021-02-08	Hospital		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	1.0 Dosage forms	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Dysgeusia	v.24.1	
Dyspnoea	v.24.1	
Malaise	v.24.1	
Swelling face	v.24.1	
Urticaria	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000938768	0	2021-02-10	2021-02-10	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
65 Years	Male	80 Inch	145 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Parenteral	0.5 ml	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain	v.24.1	
Agitation	v.24.1	
Chest pain	v.24.1	
Chills	v.24.1	
Confusional state	v.24.1	
Diarrhoea	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Disorientation	v.24.1	
Dyspnoea	v.24.1	
Fatigue	v.24.1	
Feeling abnormal	v.24.1	
Headache	v.24.1	
Hypopnoea	v.24.1	
Incorrect dose administered	v.24.1	
Lethargy	v.24.1	
Overdose	v.24.1	
Painful respiration	v.24.1	
Pyrexia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000938923	0	2021-02-11	2021-02-11	Hospital		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	1.0 Dosage forms	Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blepharospasm	v.24.1	
Sensory disturbance	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000939045	0	2021-02-12	2021-02-12	Hospital		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
69 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	1.0 ml	1 every 28 Days		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Injection site rash	v.24.1	
Injection site reaction	v.24.1	
Rash erythematous	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000939050	0	2021-02-12	2021-02-12	Hospital		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
60 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	1.0 ml	1 every 28 Days		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Injection site mass	v.24.1	8 Days
Injection site rash	v.24.1	
Injection site warmth	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000939051	0	2021-02-12	2021-02-12	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Nasopharyngitis	v.24.1	
Pain in extremity	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
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Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000939409	1	2021-02-16	2021-02-19	Hospital		Spontaneous	Other health professional

Serious report?	Death:	Disability:	Congenital Anomaly:
Serious	Yes	No	No
	Life Threatening: No	**Hospitalization:** No	**Other Medically Important Conditions:** No

Patient Information

Age	Gender	Height	Weight	Report Outcome
84 Years	Female			Fatal

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.24.1	
Dyspnoea	v.24.1	
Erythema	v.24.1	
Loss of personal independence in daily activities	v.24.1	
Rash	v.24.1	
Stridor	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Tachycardia	v.24.1	
Tachypnoea	v.24.1	
Unresponsive to stimuli	v.24.1	
Use of accessory respiratory muscles	v.24.1	
Wheezing	v.24.1	

Canada Vigilance
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Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000939843	0	2021-02-19	2021-02-19	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
31 Years	Female	157 Centimeter	59 Pound	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BIAXIN	Concomitant	Tablets					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Once		COVID-19 immunisation
TUBERCULIN PPD (MANTOUX)	Concomitant	LIQUID INTRADERMAL					
TUBERSOL	Concomitant	SOLUTION INTRADERMAL					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Erythema	v.24.1	
Pruritus	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Rash	v.24.1	
Urticaria	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

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Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000939846	0	2021-02-21	2021-02-21	Hospital		Spontaneous	Physician

Serious report?	Death:		Disability:		Congenital Anomaly:	
Not Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	

Patient Information

Age	Gender	Height	Weight	Report Outcome
43 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR			Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Rash macular	v.24.1	
Skin exfoliation	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

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Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000940311	2	2021-02-24	2021-05-03	MAH		Study	Other health professional

Serious report?	Death:	Yes	Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	

Patient Information

Age	Gender	Height	Weight	Report Outcome
95 Years	Male			Fatal

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				COVID-19 prophylaxis
ELIGARD 22.5MG	Suspect	POWDER FOR SUSPENSION, SUSTAINED-RELEASE	Subcutaneous	22.5 Milligram	1 every 3 Months		Prostate cancer
ELIGARD 22.5MG	Suspect	POWDER FOR SUSPENSION, SUSTAINED-RELEASE	Subcutaneous	22.5 Milligram	1 every 3 Months		Prostate cancer

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cardiac failure congestive	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dyspnoea	v.24.1	
Prostate cancer	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

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Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000940574	0	2021-02-25	2021-02-25	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
26 Years	Male	183 Centimeter	70 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	0.5 ml	Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pruritus	v.24.1	
Urticaria	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000940577	0	2021-02-25	2021-02-25	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
64 Years	Female	65 Inch	132 Pound	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CALCIUM	Concomitant	NOT SPECIFIED					
DUOTRAV	Concomitant	SOLUTION OPHTHALMIC					
ESTRACE	Concomitant	Tablets					
OMEGA - 3	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Once		Prophylaxis
PROVERA	Concomitant	NOT SPECIFIED					
SIMBRINZA	Concomitant	SUSPENSION OPHTHALMIC					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Burning sensation	v.24.1	
Herpes zoster	v.24.1	
Pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
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Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000940689	0	2021-02-06	2021-02-06	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
85 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood pressure decreased	v.24.1	
Fall	v.24.1	
Head injury	v.24.1	
Loss of consciousness	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

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Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000940731	0	2021-02-26	2021-02-26	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
41 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Once		Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Paraesthesia oral	v.24.1	
Throat irritation	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
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Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000940734	0	2021-02-26	2021-02-26	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
34 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Once		Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.24.1	
Sensation of foreign body	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

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Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000940906	0	2021-03-01	2021-03-01	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
37 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
OZEMPIC	Concomitant	SOLUTION SUBCUTANEOUS					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Once		COVID-19 immunisation
SYNTHROID	Concomitant	NOT SPECIFIED					
WELLBUTRIN XL	Concomitant	TABLET (EXTENDED-RELEASE)					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pain in extremity	v.24.1	5 Days

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Peripheral swelling	v.24.1	5 Days
Pruritus	v.24.1	
Urticaria	v.24.1	

Canada Vigilance
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Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000941064	0	2021-03-02	2021-03-02	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
65 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	30.0 Microgram	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pruritus	v.24.1	
Skin warm	v.24.1	
Urticaria	v.24.1	

Canada Vigilance
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Total Number of Reports:	637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000941232	0	2021-03-03	2021-03-03	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	Yes	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
78 Years	Male			Fatal

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular		Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dyspnoea	v.24.1	
General physical health deterioration	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Heart rate increased	v.24.1	
Lung disorder	v.24.1	
Oxygen saturation decreased	v.24.1	
Oxygen therapy	v.24.1	
Pneumonia aspiration	v.24.1	
Pyrexia	v.24.1	
Respiratory rate increased	v.24.1	

Canada Vigilance
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Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000941635	0	2021-03-06	2021-03-06	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
45 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
LEVOTHYROXINE	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		COVID-19 immunisation
TYLENOL	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.24.1	
Lymphadenopathy	v.24.1	
Pain in extremity	v.24.1	
Pyrexia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
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Total Number of Reports:	637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000941638	0	2021-03-05	2021-03-05	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
55 Years	Female	161 Centimeter	70 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Headache	v.24.1	
Hypoaesthesia	v.24.1	
Photophobia	v.24.1	
Tinnitus	v.24.1	

Canada Vigilance
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Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000941979	0	2021-03-09	2021-03-09	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
31 Years	Female	160 Centimeter	77 Kilogram	Recovered/resolved with sequelae

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BOTOX 50, 100 AND 200 UNIT VIALS	Concomitant	POWDER FOR SOLUTION INTRAMUSCULAR					
CIMZIA	Concomitant	Solution for injection	Subcutaneous	200.0 Milligram			
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Subcutaneous	30.0 Microgram	Once		
PLAQUENIL	Concomitant	Tablets	Unknown	200.0 Milligram			
PRISTIQ	Concomitant	TABLET (EXTENDED-RELEASE)			every 1 Days		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Back pain	v.24.1	
Cauda equina syndrome	v.24.1	
Discomfort	v.24.1	
Fatigue	v.24.1	
Gait disturbance	v.24.1	
Headache	v.24.1	
Impaired quality of life	v.24.1	
Malaise	v.24.1	
Muscle spasms	v.24.1	
Muscular weakness	v.24.1	
Myalgia	v.24.1	
Myelitis transverse	v.24.1	
Neuralgia	v.24.1	
Paraesthesia	v.24.1	
Pyrexia	v.24.1	
Urinary retention	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

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Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000942558	0	2021-03-12	2021-03-12	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
53 Years	Female	156 Centimeter	72 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ATIVAN SUBL	Concomitant	Tablets					
AVAMYS	Concomitant	SPRAY, METERED DOSE					Immunisation
CONSTELLA	Concomitant	Capsules					
LAMISIL	Concomitant	NOT SPECIFIED					
METFORMIN	Concomitant	Tablets					
PANTOLOC /01263204/	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml			

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml			
PRAZOSIN	Concomitant	Tablets					
TRULICITY 0.75MG	Concomitant	SOLUTION SUBCUTANEOUS					
TYLENOL WITH CODEINE	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Burning sensation	v.24.1	
Dyschezia	v.24.1	
Groin pain	v.24.1	
Headache	v.24.1	
Injection site pain	v.24.1	
Neck pain	v.24.1	
Pain in extremity	v.24.1	
Paraesthesia	v.24.1	
Pelvic pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000942559	1	2021-03-12	2021-03-16	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
87 Years	Female		52 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Dehydration	v.24.1	
Disorientation	v.24.1	
Dizziness	v.24.1	
Nausea	v.24.1	
Pollakiuria	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Renal impairment	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000942560	0	2021-03-12	2021-03-12	Hospital		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
44 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml			Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.24.1	
Chills	v.24.1	
Diarrhoea	v.24.1	
Dizziness	v.24.1	
Dyspnoea	v.24.1	
Fatigue	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Nausea	v.24.1	12 Days
Pain	v.24.1	
Pyrexia	v.24.1	
Vomiting	v.24.1	
Wheezing	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000942561	0	2021-03-12	2021-03-12	Community		Spontaneous	Physician

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Rash	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000942562	0	2021-03-13	2021-03-13	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
79 Years	Female		60 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	0.5 ml			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Inflammation	v.24.1	
Injection site discomfort	v.24.1	
Injection site erythema	v.24.1	
Pruritus	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000942578	0	2021-03-15	2021-03-15	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
32 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Galactostasis	v.24.1	
Maternal exposure during breast feeding	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000942579	0	2021-03-15	2021-03-15	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
50 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.5 ml			COVID-19 prophylaxis
RANITIDINE	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Chills	v.24.1	
Dizziness	v.24.1	
Headache	v.24.1	
Skin warm	v.24.1	
Tremor	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000942581	0	2021-03-15	2021-03-15	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
66 Years	Female	64 Inch	170 Pound	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Once		Prophylaxis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Erythema	v.24.1	
Oedema peripheral	v.24.1	1 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000942583	0	2021-03-15	2021-03-15	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
27 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	30.0 Microgram	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bell's palsy	v.24.1	
Eyelid function disorder	v.24.1	
Lacrimation increased	v.24.1	
Taste disorder	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000942595	0	2021-03-15	2021-03-15	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
63 Years	Female	163 Centimeter	132 Pound	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 8 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR		0.5 ml	Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.24.1	
Cough	v.24.1	
Dysgeusia	v.24.1	
Headache	v.24.1	
Nausea	v.24.1	
Vaccination site movement impairment	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000942703	0	2021-03-16	2021-03-16	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
54 Years	Female	64 Inch	126 Pound	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR		0.3 ml	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.24.1	
Cold sweat	v.24.1	
Fatigue	v.24.1	
Headache	v.24.1	
Pain	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000942706	0	2021-03-16	2021-03-16	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female	166 Centimeter	64 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVERSYL	Concomitant	Tablets		8.0 Milligram	1 every 1 Days		
LIPITOR	Concomitant	Tablets	Unknown	50.0 Milligram	1 every 1 Days		
METOPROLOL	Concomitant	Tablets	Unknown	25.0 Milligram	0 every 2 Days		
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR		0.3 ml	Once		
PLAVIX	Concomitant	Tablets		75.0 Milligram	1 every 1 Days		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypoaesthesia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000942715	0	2021-03-16	2021-03-16	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
79 Years	Male	69 Inch	170 Pound	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR		0.5 ml	Once	60.0 Seconds	COVID-19

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cerebrovascular accident	v.24.1	1 Days
Ischaemic stroke	v.24.1	1 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000942718	0	2021-03-16	2021-03-16	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
29 Years	Female	63 Inch	170 Pound	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Once		Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Peripheral swelling	v.24.1	
Pyrexia	v.24.1	
Swelling	v.24.1	
Swelling face	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000942721	0	2021-03-16	2021-03-16	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
35 Years	Female		63 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR			Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Electric shock sensation	v.24.1	2 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000942883	0	2021-03-17	2021-03-17	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
44 Years	Female	165 Centimeter	312 Pound	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Other		Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain	v.24.1	
Condition aggravated	v.24.1	
Crohn's disease	v.24.1	
Diarrhoea	v.24.1	
Pyrexia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000942884	0	2021-03-17	2021-03-17	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
78 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	30.0 Microgram	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Periorbital swelling	v.24.1	
Pruritus	v.24.1	
Rash	v.24.1	
Urticaria	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000942889	0	2021-03-17	2021-03-17	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
74 Years	Female	170 Centimeter	89 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AMLODIPINE	Concomitant	Tablets					
CLOBETASOL	Concomitant	LOTION					
LOSARTAN	Concomitant	Tablets					
PANTOPRAZOLE	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR			Once		Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pulmonary embolism	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000943029	0	2021-03-18	2021-03-18	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
41 Years	Female	174 Centimeter	78 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Appendicectomy	v.24.1	
Appendicitis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000943032	0	2021-03-18	2021-03-18	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
83 Years	Female	163 Centimeter	72 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AMLODIPINE	Concomitant	Tablets					
BREO ELLIPTA	Concomitant	INHALATION	Unknown				
LORAZEPAM	Concomitant	NOT SPECIFIED					
NITROGLYCERIN	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Subcutaneous		Once		COVID-19 immunisation
PREDNISONE	Concomitant	NOT SPECIFIED					
SALBUTAMOL	Concomitant	NOT SPECIFIED					
SPIRIVA RESPIMAT	Concomitant	SOLUTION INHALATION					
TELMISARTAN	Concomitant	Tablets					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Back pain	v.24.1	
Deep vein thrombosis	v.24.1	
Pain in extremity	v.24.1	
Peripheral swelling	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000943098	1	2021-03-19	2021-06-03	MAH		Study	Other health professional

Serious report?	Death:	Yes	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
85 Years	Male			Fatal

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				COVID-19 prophylaxis
ELIGARD 30 MG	Suspect	POWDER FOR SUSPENSION, SUSTAINED-RELEASE	Subcutaneous	30.0 Milligram	1 every 4 Months		Prostate cancer
ELIGARD 30 MG	Suspect	POWDER FOR SUSPENSION, SUSTAINED-RELEASE	Subcutaneous	30.0 Milligram	1 every 4 Months		Prostate cancer

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Disease progression	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.24.1	
Fall	v.24.1	
Malaise	v.24.1	
Prostate cancer	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000943101	0	2021-03-20	2021-03-20	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
77 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETAMINOPHEN	Concomitant	NOT SPECIFIED					
ASA 80 MG	Concomitant	Tablets		80.0 Milligram	1 every 1 Days		
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular		Once		COVID-19 immunisation
CRESTOR - 20MG	Concomitant	Tablets					
METOPROLOL FILM-COATED 50MG TABLET	Concomitant	Tablets		50.0 Milligram	1 every 1 Days		
PANTOLOC /01263204/	Concomitant	NOT SPECIFIED					
VITAMIN D	Concomitant	NOT SPECIFIED		1000.0 IU (International Unit)			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dyspnoea	v.24.1	
Pleuritic pain	v.24.1	
Pulmonary embolism	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000943104	0	2021-03-21	2021-03-21	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
31 Years	Female	170 Centimeter	144 Pound	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
GRAVOL	Concomitant	Tablets					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR			Once		
TEMAZEPAM	Concomitant	Capsules					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Oropharyngeal pain	v.24.1	
Palpitations	v.24.1	
Rash	v.24.1	
Tachycardia	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Urticaria	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000943108	0	2021-03-21	2021-03-21	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
62 Years	Female	155 Centimeter	160 Pound	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Once		COVID-19 immunisation
SYNTHROID TAB 88MCG	Concomitant	Tablets		80.0 Microgram	1 every 1 Days		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.24.1	
Lymph node pain	v.24.1	
Lymphadenopathy	v.24.1	
Musculoskeletal stiffness	v.24.1	
Neck pain	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000943110	0	2021-03-21	2021-03-21	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
64 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Oral		Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pruritus	v.24.1	
Rash macular	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000943112	1	2021-03-19	2021-03-23	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
81 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR		0.3 ml	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Phlebitis superficial	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000943113	0	2021-03-19	2021-03-19	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
46 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
FERROUS SULFATE TAB 300MG	Suspect	Tablets		300.0 Milligram			
LORAZEPAM	Suspect	Tablets		0.5 Milligram	1 every 1 Days		
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Once		COVID-19 immunisation
RANITIDINE TAB 150MG	Suspect	Tablets		150.0 Milligram	2 every 1 Days		
SANDOZ OLOPATADINE 0.2%	Suspect	SOLUTION OPHTHALMIC					
VALACYCLOVIR	Suspect	Tablets		500.0 Milligram	2 every 1 Days		
XERESE	Suspect	Cream					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Inflammation	v.24.1	
Oedema peripheral	v.24.1	
Pain	v.24.1	
Pharyngeal paraesthesia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000943143	0	2021-03-21	2021-03-21	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
72 Years	Male	178 Centimeter	77 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BISOPROLOL	Concomitant	Tablets					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR			Once		COVID-19 immunisation
XARELTO	Suspect	Tablets	Oral	20.0 Milligram	1 every 1 Days		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Drug interaction	v.24.1	6 Days
Impaired healing	v.24.1	
Inflammation of wound	v.24.1	
Procedural site reaction	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Wound haemorrhage	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000943240	0	2021-03-22	2021-03-22	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
62 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR			Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Ankle fracture	v.24.1	
Chills	v.24.1	
Headache	v.24.1	
Ligament injury	v.24.1	
Ligament sprain	v.24.1	
Myalgia	v.24.1	
Syncope	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000943346	0	2021-03-23	2021-03-23	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
36 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	30.0 ml	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Alopecia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000943350	0	2021-03-23	2021-03-23	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Presyncope	v.24.1	
Pruritus	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000943356	0	2021-03-23	2021-03-23	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CONTRACEPTIVES	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Injection site oedema	v.24.1	
Injection site pain	v.24.1	
Injection site warmth	v.24.1	
Lymph node pain	v.24.1	
Lymphadenopathy	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000943606	0	2021-03-25	2021-03-25	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
41 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
GABAPENTIN	Concomitant	NOT SPECIFIED					
PANTOPRAZOLE	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Once	28.0 Days	Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dysphonia	v.24.1	
Laryngospasm	v.24.1	
Pharyngeal swelling	v.24.1	
Throat tightness	v.24.1	6 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000943608	0	2021-03-25	2021-03-25	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular		Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Injection site erythema	v.24.1	
Injection site rash	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000943611	0	2021-03-25	2021-03-25	Community		Spontaneous	Physician

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
66 Years	Female	162 Centimeter	64 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.5 ml	Once		Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Nausea	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000943613	0	2021-03-25	2021-03-25	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect				Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.24.1	
Delirium	v.24.1	
Dysstasia	v.24.1	
Illness	v.24.1	
Pyrexia	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000943699	0	2021-03-26	2021-03-26	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
76 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETAMINOPHEN	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	30.0 Microgram	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.24.1	
Cold sweat	v.24.1	
Fatigue	v.24.1	
Night sweats	v.24.1	
Pain in extremity	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pyrexia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000943700	0	2021-03-29	2021-03-29	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
49 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BACLOFEN	Concomitant	NOT SPECIFIED					
CLONAZEPAM	Concomitant	Tablets					
GABAPENTIN	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dysphonia	v.24.1	
Fatigue	v.24.1	
Myalgia	v.24.1	
Nasal congestion	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Productive cough	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000943701	0	2021-03-29	2021-03-29	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
30 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Parenteral	0.5 ml	Once		COVID-19 prophylaxis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Diarrhoea	v.24.1	
Malaise	v.24.1	
Myalgia	v.24.1	
Oropharyngeal pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000943712	0	2021-03-27	2021-03-27	Hospital		Spontaneous	Physician

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
67 Years	Female	150 Centimeter	55 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect			1.0 Dosage forms	Once		Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cellulitis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000943719	0	2021-03-28	2021-03-28	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
78 Years	Male	68 Inch	200 Pound	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ATORVASTATIN	Concomitant	Tablets					
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect						COVID-19 prophylaxis
ELIQUIS	Concomitant	Tablets					
ELMIRON	Concomitant	Capsules					
PRO-BISOPROLOL - 5	Concomitant	Tablets					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Erythema	v.24.1	
Myalgia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000943729	0	2021-03-26	2021-03-26	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
81 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETYLSALICYLIC ACID	Concomitant	NOT SPECIFIED	Unknown	80.0 Milligram			
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular		Once		COVID-19 prophylaxis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Eyelid haematoma	v.24.1	
Haematoma	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000943801	0	2021-03-27	2021-03-27	Community		Spontaneous	Physician

Serious report?	Death:		Disability:		Congenital Anomaly:	
Not Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
72 Years	Female	152 Centimeter	61 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect				Once		Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cellulitis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000943876	0	2021-03-29	2021-03-29	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
76 Years	Female	122 Centimeter		Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular				COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Injection site inflammation	v.24.1	
Injection site rash	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000943877	0	2021-03-29	2021-03-29	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
79 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Parenteral	0.5 ml	Once		COVID-19 prophylaxis
STATINS	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dysphonia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000943878	0	2021-03-29	2021-03-29	Community		Spontaneous	Pharmacist

Serious report?	Death:		Disability:		Congenital Anomaly:	
Not Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
42 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Diarrhoea	v.24.1	
Dizziness	v.24.1	
Nausea	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000943885	0	2021-03-29	2021-03-29	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
33 Years	Female	163 Centimeter	83 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ANTIHISTAMINIC DRUGS	Concomitant	NOT SPECIFIED					
DYMISTA NASENSPRAY, SUSPENSION	Concomitant						
INSULIN	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR		0.3 ml	Once		Immunisation
SINGULAIR	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Rash pruritic	v.24.1	
Urticaria	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000943886	0	2021-03-29	2021-03-29	Community		Spontaneous	Physician

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:	Yes	Hospitalization:		Other Medically Important Conditions:	

Patient Information

Age	Gender	Height	Weight	Report Outcome
41 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular		Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dyspnoea	v.24.1	
Nausea	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000943892	0	2021-03-29	2021-03-29	Community		Spontaneous	Physician

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:	Yes	Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
66 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	1.0 Dosage forms	Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000944006	0	2021-03-30	2021-03-30	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
49 Years	Male	72 Inch	90 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR			Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain	v.24.1	
Asthenia	v.24.1	
Chest pain	v.24.1	
Headache	v.24.1	
Malaise	v.24.1	
Vertigo	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000944015	0	2021-03-30	2021-03-30	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
72 Years	Female	64 Inch	162 Pound	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR					COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Mononeuritis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000944018	0	2021-03-30	2021-03-30	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
68 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pain in extremity	v.24.1	
Periorbital swelling	v.24.1	
Vision blurred	v.24.1	
Visual impairment	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000944023	0	2021-03-30	2021-03-30	Hospital		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
68 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR					
DAPAGLIFLOZIN	Concomitant						
DULAGLUTIDE	Concomitant						
EZETIMIBE	Concomitant	Tablets					
GLICLAZIDE	Concomitant	Tablets					
METFORMIN	Concomitant	Tablets					
PRAVASTATIN SODIUM	Concomitant	Tablets					
RAMIPRIL	Concomitant	NOT SPECIFIED					
VITAMIN B12 [HYDROXOCOBALAMIN]	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cerebrovascular accident	v.24.1	
Ischaemic stroke	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000944188	0	2021-03-31	2021-03-31	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
49 Years	Female	152 Centimeter	75 Pound	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.5 ml	Once		Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Chest pain	v.24.1	
Dyspnoea	v.24.1	
Endometrial cancer	v.24.1	
Haemoglobin decreased	v.24.1	
Heavy menstrual bleeding	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Transfusion	v.24.1	
Vaginal haemorrhage	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000944189	0	2021-03-31	2021-03-31	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
51 Years	Female	154 Centimeter	69 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular				COVID-19 prophylaxis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Erythema	v.24.1	
Myalgia	v.24.1	
Neck pain	v.24.1	
Pain	v.24.1	
Swelling	v.24.1	

Canada Vigilance
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Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000944194	0	2021-03-31	2021-03-31	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
66 Years	Male	165 Centimeter	61 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect				Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Injection site rash	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
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Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000944352	0	2021-04-01	2021-04-01	Hospital		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
94 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
LEVOTHYROXINE	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		
ZOPICLONE	Concomitant	Tablets					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Alanine aminotransferase increased	v.24.1	
Areflexia	v.24.1	
Asthenia	v.24.1	
Blood creatine phosphokinase increased	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
C-reactive protein increased	v.24.1	
Fall	v.24.1	
Fatigue	v.24.1	
Guillain-Barre syndrome	v.24.1	
Inflammation	v.24.1	
Left ventricular hypertrophy	v.24.1	
Mobility decreased	v.24.1	
Muscle atrophy	v.24.1	
Muscular weakness	v.24.1	
Nerve conduction studies abnormal	v.24.1	
Oedema	v.24.1	
Peripheral motor neuropathy	v.24.1	
Peripheral sensory neuropathy	v.24.1	
Sensory loss	v.24.1	
Troponin increased	v.24.1	
White blood cell count increased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000944354	0	2021-04-02	2021-04-02	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
82 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dementia	v.24.1	
Fatigue	v.24.1	
Feeling abnormal	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000944375	0	2021-04-03	2021-04-03	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
22 Years	Male	74 Inch	183 Pound	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Rash	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

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Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000944379	0	2021-04-05	2021-04-05	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
29 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect				Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Herpes zoster	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

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Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000944381	0	2021-04-05	2021-04-05	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
61 Years	Male	70 Inch	172 Pound	Recovering/resolving

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.5 ml	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain upper	v.24.1	
Muscle spasms	v.24.1	
Nausea	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

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Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000944383	0	2021-04-05	2021-04-05	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
25 Years	Female	62 Inch	114 Pound	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Tinnitus	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

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Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000944391	0	2021-04-01	2021-04-01	Hospital		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
51 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Topical	0.3 ml			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Atonic seizures	v.24.1	
Blood pressure increased	v.24.1	
Change of bowel habit	v.24.1	
Condition aggravated	v.24.1	
Eye movement disorder	v.24.1	
Hypophagia	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Unresponsive to stimuli	v.24.1	

Canada Vigilance
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Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000944393	0	2021-04-01	2021-04-01	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.5 ml			Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Rash	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

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Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000944394	0	2021-04-02	2021-04-02	Hospital		Spontaneous	Physician

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
75 Years	Male			Recovering/resolving

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	0.5 ml			Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cellulitis	v.24.1	
Injection site erythema	v.24.1	
Injection site swelling	v.24.1	
Pruritus	v.24.1	
Urticaria	v.24.1	

Canada Vigilance
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Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000944395	0	2021-04-02	2021-04-02	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death: Yes	Disability:	Congenital Anomaly:
Serious	Life Threatening:	Hospitalization:	Other Medically Important Conditions:

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Fatal

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cerebrovascular accident	v.24.1	

Canada Vigilance
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Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000944399	0	2021-04-03	2021-04-03	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
66 Years	Female	150 Centimeter	55 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect				Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Skin reaction	v.24.1	

Canada Vigilance
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Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000944406	0	2021-04-05	2021-04-05	Community		Spontaneous	Nurse

Serious report?	Death:		Disability:		Congenital Anomaly:	
Not Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
88 Years	Female	154 Centimeter	53 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETYLSALICYLIC ACID	Concomitant	Tablets	Unknown				
ATORVASTATIN	Concomitant	Tablets					
CIPRALEX	Concomitant	Tablets					
LACTULOSE	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR			Once		COVID-19 immunisation
RABEPRAZOLE	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.24.1	
Tremor	v.24.1	

Canada Vigilance
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Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000944416	0	2021-04-05	2021-04-05	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Erythema	v.24.1	
Injection site erythema	v.24.1	
Injection site pain	v.24.1	
Injection site swelling	v.24.1	
Paraesthesia	v.24.1	
Pruritus	v.24.1	
Rash	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Urticaria	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
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Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000944592	0	2021-04-06	2021-04-06	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
79 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	0.5 ml			Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Erythema	v.24.1	
Injection site cellulitis	v.24.1	
Injection site erythema	v.24.1	
Injection site inflammation	v.24.1	
Pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

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Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000944593	0	2021-04-06	2021-04-06	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
53 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Conjunctival haemorrhage	v.24.1	
Eye haemorrhage	v.24.1	
Eye pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000944595	0	2021-04-06	2021-04-06	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
40 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
LEVOTHYROXINE	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				COVID-19 prophylaxis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.24.1	1 Days
Nausea	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000944599	0	2021-04-06	2021-04-06	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
73 Years	Female	60 Inch	65 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ARTHROTEC	Concomitant	Tablets					
CRESTOR - 20MG	Concomitant	Tablets					
CYANOCOBALAMIN INJ 1000MCG/ML	Concomitant	LIQUID INTRAMUSCULAR					
ERYTHROMYCIN	Concomitant	NOT SPECIFIED					
FLONASE	Concomitant	NOT SPECIFIED	Unknown				
HYDROCORTISONE	Concomitant	Suppository					
PENICILLIN	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR			Once		COVID-19 immunisation
VALTREX	Concomitant	Tablets					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Feeling cold	v.24.1	
Hypoaesthesia	v.24.1	
Palpitations	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000944600	0	2021-04-06	2021-04-06	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
60 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR			Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Tinnitus	v.24.1	
Vision blurred	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000944807	1	2021-04-07	2021-04-07	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
90 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	30.0 Microgram	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Injection site reaction	v.24.1	
Muscle spasms	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000944808	0	2021-04-07	2021-04-07	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	30.0 Microgram	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pain in extremity	v.24.1	
Pruritus	v.24.1	
Rash erythematous	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000944816	0	2021-04-07	2021-04-07	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
40 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR			Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest discomfort	v.24.1	
Dyspnoea	v.24.1	
Guillain-Barre syndrome	v.24.1	
Neuropathy peripheral	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000944820	0	2021-04-07	2021-04-07	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
66 Years	Female	162 Centimeter	86 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect				Once		COVID-19 prophylaxis
PENICILLIN	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Alanine aminotransferase increased	v.24.1	
Petechiae	v.24.1	
Vasculitis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000944822	0	2021-04-07	2021-04-07	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male	167 Centimeter	87 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect				Once		
INSULIN	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood glucose increased	v.24.1	
Diabetes mellitus inadequate control	v.24.1	
Drug interaction	v.24.1	
Ketoacidosis	v.24.1	
Malaise	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Metabolic disorder	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000944995	0	2021-04-08	2021-04-08	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
86 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	30.0 Microgram	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Chest discomfort	v.24.1	
Gait disturbance	v.24.1	
Malaise	v.24.1	
Myalgia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000944996	0	2021-04-08	2021-04-08	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
64 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR			Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Chest discomfort	v.24.1	
Fatigue	v.24.1	
General physical condition abnormal	v.24.1	
Myalgia	v.24.1	
Night sweats	v.24.1	
Pyrexia	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Synovitis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000944998	0	2021-04-08	2021-04-08	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
51 Years	Female	69 Inch	240 Pound	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect				Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cellulitis	v.24.1	
Erythema	v.24.1	
Feeling hot	v.24.1	
Infection	v.24.1	
Peripheral swelling	v.24.1	
Rash macular	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000945254	0	2021-04-09	2021-04-09	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
35 Years	Female	170 Centimeter	58 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dermatitis	v.24.1	
Rash erythematous	v.24.1	
Rash pruritic	v.24.1	7 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000945256	0	2021-04-09	2021-04-09	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
33 Years	Female	170 Centimeter	63 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR		3.0 ml			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Balance disorder	v.24.1	
Blood pressure decreased	v.24.1	
Cold sweat	v.24.1	
Dizziness	v.24.1	
Heart rate decreased	v.24.1	
Syncope	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Tremor	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
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Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000945257	0	2021-04-09	2021-04-09	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
71 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect			0.3 ml	Once		Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cellulitis	v.24.1	
Erythema	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000945258	0	2021-04-10	2021-04-10	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
67 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	100.0 Microgram			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Erythema	v.24.1	
Pain in extremity	v.24.1	
Peripheral swelling	v.24.1	
Pruritus	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000945259	0	2021-04-11	2021-04-11	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
73 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Diarrhoea	v.24.1	
Hyperhidrosis	v.24.1	
Syncope	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000945260	0	2021-04-11	2021-04-11	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
62 Years	Female	64 Inch	125 Pound	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect						COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dysgeusia	v.24.1	
Fatigue	v.24.1	
Headache	v.24.1	
Paraesthesia oral	v.24.1	
Tongue discomfort	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000945261	0	2021-04-11	2021-04-11	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
54 Years	Female	165 Centimeter		Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Once		
SHINGRIX	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.5 ml	Once		Herpes zoster immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	1 Days
Decreased appetite	v.24.1	1 Days
Dizziness	v.24.1	1 Days
Nausea	v.24.1	1 Days
Pyrexia	v.24.1	1 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000945265	0	2021-04-09	2021-04-09	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
73 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypoaesthesia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000945266	0	2021-04-09	2021-04-09	Community		Spontaneous	Other health professional

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
81 Years	Female		59 Kilogram	Recovering/resolving

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR			Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Diarrhoea	v.24.1	
Faeces soft	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000945270	0	2021-04-10	2021-04-10	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
66 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR			Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bell's palsy	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000945271	0	2021-04-09	2021-04-09	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	Yes	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male			Fatal

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect				Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pneumonia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000945483	1	2021-04-12	2021-04-14	Community		Spontaneous	Consumer/other non health professional

Serious report?
Serious

Death:	Yes	**Disability:**	No	**Congenital Anomaly:**	No
Life Threatening:	No	**Hospitalization:**	No	**Other Medically Important Conditions:**	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
89 Years	Male	155 Centimeter	55 Kilogram	Fatal

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_03986299

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
APO-LEVOCARB	Concomitant	Tablets					
AURO-MIRTAZAPINE OD	Concomitant	TABLET (ORALLY DISINTEGRATING)					
FINASTERIDE	Concomitant	Tablets					
PANTOPRAZOLE	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR		0.3 ml			
TAMSULOSIN CR	Concomitant	TABLET (EXTENDED-RELEASE)					
TEVA-LOPERAMIDE	Concomitant	Tablets					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cerebrovascular accident	v.24.1	
Loss of consciousness	v.24.1	
Nervous system disorder	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000945485	0	2021-04-12	2021-04-12	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
58 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular		Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Balance disorder	v.24.1	
Dizziness	v.24.1	
Ear discomfort	v.24.1	
Ear discomfort	v.24.1	
Feeling cold	v.24.1	
Myalgia	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pain in extremity	v.24.1	
Tinnitus	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000945490	0	2021-04-12	2021-04-12	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR			Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Arthritis	v.24.1	
Fatigue	v.24.1	
Hypersensitivity	v.24.1	
Hypoaesthesia	v.24.1	
Myalgia	v.24.1	
Paraesthesia	v.24.1	
Pyrexia	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Rash	v.24.1	
Skin reaction	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000945585	0	2021-04-13	2021-04-13	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
66 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR					COVID-19

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.24.1	
Influenza like illness	v.24.1	
Myalgia	v.24.1	
Pyrexia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000945667	0	2021-04-13	2021-04-13	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
78 Years	Female	161 Centimeter	70 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASPIRIN REGIMEN BAYER 81 MG TABLETS	Concomitant	Tablets	Unknown				
AVAPRO	Concomitant	Tablets					
ELTROXIN TAB 300MCG	Concomitant	Tablets					
LEVAQUIN	Concomitant	NOT SPECIFIED					
METFORMIN	Concomitant	Tablets					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		COVID-19 immunisation
RUPALL	Concomitant	Tablets					
TEGRETOL - SUS 100MG/5ML	Concomitant	SUSPENSION ORAL					
ZITHROMAX	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dermatitis	v.24.1	
Rash pruritic	v.24.1	
Skin abrasion	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000945668	0	2021-04-13	2021-04-13	Community		Spontaneous	Physician

Serious report?	Death:		Disability:		Congenital Anomaly:	
Not Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
76 Years	Female	63 Inch	120 Pound	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000945669	0	2021-04-13	2021-04-13	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
32 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Eyelid ptosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000945681	0	2021-04-13	2021-04-13	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
57 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR					COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Body temperature increased	v.24.1	
Neutrophil count increased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000945685	0	2021-04-13	2021-04-13	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
81 Years	Female	66 Inch	153 Pound	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
GLUCOPHAGE	Concomitant	Tablets					
NEURONTIN	Concomitant	Capsules					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				COVID-19 immunisation
TYLENOL	Concomitant	ELIXIR					
VITAMIN D	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Bone pain	v.24.1	22 Days
Condition aggravated	v.24.1	
Headache	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Lymphoedema	v.24.1	
Muscle contractions involuntary	v.24.1	
Myalgia	v.24.1	
Petit mal epilepsy	v.24.1	
Spinal pain	v.24.1	
Tic	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000945832	0	2021-04-14	2021-04-14	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
47 Years				Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
FINASTERIDE	Concomitant	Tablets					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Subcutaneous				COVID-19 immunisation
TRUVADA	Concomitant	Tablets					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Alopecia areata	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000945833	0	2021-04-14	2021-04-14	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
67 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.5 ml	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blister	v.24.1	
Pigmentation disorder	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000945834	0	2021-04-14	2021-04-14	Hospital		Spontaneous	Nurse

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
41 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Subcutaneous		Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	14 Days
Hypertension	v.24.1	14 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000945836	0	2021-04-14	2021-04-14	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
80 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		COVID-19 immunisation
RAMIPRIL	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000945843	0	2021-04-14	2021-04-14	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
61 Years	Female	159 Centimeter	89 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect				Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dysgeusia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000945846	0	2021-04-14	2021-04-14	Community		Spontaneous	Physician

Serious report?	Death:		Disability:		Congenital Anomaly:	
Not Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
57 Years	Female		59 Kilogram	Recovering/resolving

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR			Once		COVID-19 immunisation
CIPRALEX -5MG	Concomitant	Tablets					
ELTROXIN	Concomitant	Tablets					
VENTOLIN INHALER [23564]	Concomitant						
VITAMIN B12	Concomitant	Tablets					
VITAMIN D	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal discomfort	v.24.1	
Headache	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Malaise	v.24.1	
Nausea	v.24.1	
Pyrexia	v.24.1	
Rash	v.24.1	
Rash pruritic	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000945849	0	2021-04-14	2021-04-14	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
58 Years	Female		60 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular		Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dermatitis allergic	v.24.1	
Rash	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000945887	0	2021-04-14	2021-04-14	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
44 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.24.1	14 Days
Vertigo	v.24.1	14 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000946030	0	2021-04-15	2021-04-15	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
73 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Erythema	v.24.1	
Feeling hot	v.24.1	
Hypertension	v.24.1	
Hypoaesthesia	v.24.1	
Peripheral coldness	v.24.1	
Tremor	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000946032	0	2021-04-15	2021-04-15	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
79 Years	Female	149 Centimeter	73 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASA	Concomitant	NOT SPECIFIED	Unknown				
FUROSEMIDE	Concomitant	NOT SPECIFIED	Unknown				
MONOPROST SINGLE-DOSE	Concomitant	SOLUTION OPHTHALMIC					
NORVASC	Concomitant	Tablets					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Parenteral				Immunisation
VENTOLIN	Concomitant	NOT SPECIFIED					
VITAMIN D3 1000 IU TABLETS	Concomitant	Tablets					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Diarrhoea	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Flushing	v.24.1	
Hypersensitivity	v.24.1	
Increased upper airway secretion	v.24.1	
Rash macular	v.24.1	
Skin warm	v.24.1	
Throat tightness	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000946033	0	2021-04-15	2021-04-15	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Injection site mass	v.24.1	
Pain in extremity	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000946036	0	2021-04-15	2021-04-15	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
59 Years	Male	173 Centimeter	103 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETAMINOPHEN	Concomitant	NOT SPECIFIED					
AIMOVIG SINGLE-USE PRE-FILLED AUTOINJECTOR	Concomitant	SOLUTION SUBCUTANEOUS					
ALLOPURINOL	Concomitant	Tablets					
AMLODIPINE TAB 10MG	Concomitant	Tablets					
ASA 81 MG	Concomitant	TABLET (DELAYED-RELEASE)					
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR		0.5 ml	Once		Immunisation
AVELOX	Concomitant	NOT SPECIFIED					
CALCIUM	Concomitant	NOT SPECIFIED					
CYMBALTA	Concomitant	CAPSULE, DELAYED RELEASE					

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
DIVALPROEX	Concomitant	TABLET (ENTERIC-COATED)					
ERYTHROMYCIN	Concomitant	NOT SPECIFIED					
FERROUS FUMARATE SCT TAB 300MG	Concomitant	Tablets					
LINAGLIPTIN	Concomitant						
LIPITOR	Concomitant	Tablets					
PANTOPRAZOLE	Concomitant	POWDER FOR SOLUTION INTRAVENOUS					
PENICILLIN	Concomitant	NOT SPECIFIED					
PREGABALIN	Concomitant	Capsules					
VENTOLIN	Concomitant	NOT SPECIFIED					
VITAMIN B12 TAB 100MCG	Concomitant	Tablets					
VITAMIN D	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Heart rate increased	v.24.1	
Pallor	v.24.1	
Paraesthesia oral	v.24.1	
Pharyngeal paraesthesia	v.24.1	
Tremor	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000946040	1	2021-04-15	2021-04-19	Hospital		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
71 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Deep vein thrombosis	v.24.1	
Pain in extremity	v.24.1	
Peripheral swelling	v.24.1	
Superficial vein thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000946042	0	2021-04-15	2021-04-15	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
63 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR		0.5 ml	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Paraesthesia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000946049	0	2021-04-15	2021-04-15	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
86 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BISACODYL	Concomitant	NOT SPECIFIED					
CLOTRIMAZOLE	Concomitant	NOT SPECIFIED					
COLACE	Concomitant	NOT SPECIFIED					
FOLIC ACID	Concomitant	NOT SPECIFIED					
HYDROCORTISONE	Concomitant	NOT SPECIFIED					
LYRICA	Concomitant	Capsules					
METAMUCIL	Concomitant	NOT SPECIFIED					
METHOTREXATE	Concomitant	NOT SPECIFIED	Oral				
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	0.5 ml			COVID-19 immunisation
PERCOCET	Concomitant	Tablets	Unknown				
PREDNISONE	Concomitant	NOT SPECIFIED					

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PROLIA	Concomitant	SOLUTION SUBCUTANEOUS					
SENOKOT	Concomitant	NOT SPECIFIED					
VENLAFAXINE XR	Concomitant	CAPSULE, EXTENDED RELEASE					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Injection site inflammation	v.24.1	12 Days
Injection site pain	v.24.1	12 Days
Injection site pruritus	v.24.1	12 Days
Injection site rash	v.24.1	12 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000946251	0	2021-04-19	2021-04-19	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
75 Years	Male	183 Centimeter	97 Kilogram	Recovering/resolving

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
LIXIANA	Concomitant	Tablets					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				COVID-19 immunisation
TIAZAC [DILTIAZEM HYDROCHLORIDE]	Concomitant	NOT SPECIFIED					
TOLOXIN	Concomitant	Tablets					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bell's palsy	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000946252	0	2021-04-18	2021-04-18	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
59 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.24.1	
Hypertension	v.24.1	
Malaise	v.24.1	
Paraesthesia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000946254	0	2021-04-17	2021-04-17	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
65 Years	Female		47 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Disorientation	v.24.1	
Facial discomfort	v.24.1	
Hypersensitivity	v.24.1	
Hypoacusis	v.24.1	
Rales	v.24.1	
Tension headache	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Throat tightness	v.24.1	
Tremor	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000946255	0	2021-04-16	2021-04-16	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
80 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	0.5 ml	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pruritus	v.24.1	
Rash	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000946256	0	2021-04-16	2021-04-16	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
84 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	0.5 ml	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Injection site rash	v.24.1	
Injection site warmth	v.24.1	
Rash erythematous	v.24.1	
Rash papular	v.24.1	
Rash pruritic	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000946257	0	2021-04-17	2021-04-17	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
74 Years	Female	152 Centimeter	86 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Erythema	v.24.1	
Pain	v.24.1	
Pruritus	v.24.1	
Swelling	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000946258	0	2021-04-16	2021-04-16	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
59 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.5 ml	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Rash	v.24.1	
Rash erythematous	v.24.1	
Rash pruritic	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000946262	0	2021-04-16	2021-04-16	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
54 Years	Female	157 Centimeter	61 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR			Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Injection site cellulitis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000946264	0	2021-04-16	2021-04-16	Community		Spontaneous	Nurse

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
57 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR			Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Injection site reaction	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000946265	0	2021-04-16	2021-04-16	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
83 Years	Female	65 Inch	160 Pound	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Parenteral				COVID-19 prophylaxis
CRESTOR	Concomitant	Tablets					
SYNTHROID	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blister	v.24.1	
Erythema	v.24.1	
Pain	v.24.1	
Swelling	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000946268	0	2021-04-16	2021-04-16	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
70 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVERSYL	Concomitant	Tablets					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR		0.3 ml			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Injection site haemorrhage	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000946270	0	2021-04-16	2021-04-16	Community		Spontaneous	Pharmacist

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
81 Years	Male		102 Kilogram	Recovering/resolving

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASAPHEN	Concomitant	NOT SPECIFIED					
ATORVASTATIN	Concomitant	Tablets					
IRBESARTAN	Concomitant	Tablets	Unknown				
METFORMIN	Concomitant	Tablets					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Once		COVID-19 prophylaxis
SYNTHROID	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Herpes zoster	v.24.1	
Pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000946278	0	2021-04-16	2021-04-16	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
54 Years	Female	66 Inch	170 Pound	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR					COVID-19 prophylaxis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000946427	0	2021-04-19	2021-04-19	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
68 Years	Male	170 Centimeter		Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Condition aggravated	v.24.1	
Tinnitus	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000946429	0	2021-04-19	2021-04-19	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR			Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	
Headache	v.24.1	
Pyrexia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000946431	0	2021-04-19	2021-04-19	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR			Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Diarrhoea	v.24.1	
Dyspnoea	v.24.1	
Headache	v.24.1	
Hyperhidrosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000946432	0	2021-04-19	2021-04-19	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
57 Years	Female	173 Centimeter		Recovered/resolved with sequelae

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular		Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Back pain	v.24.1	
Chills	v.24.1	
Headache	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000946434	1	2021-04-19	2021-05-04	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
62 Years	Male			Recovered/resolved with sequelae

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR			Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Aphasia	v.24.1	
Cerebrovascular accident	v.24.1	
Fatigue	v.24.1	
Pain in extremity	v.24.1	
Speech disorder	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000946437	0	2021-04-19	2021-04-19	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
71 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Herpes zoster	v.24.1	
Post herpetic neuralgia	v.24.1	
Rash	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000946438	0	2021-04-19	2021-04-19	Community		Spontaneous	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
44 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Eye swelling	v.24.1	
Swelling	v.24.1	
Swelling of eyelid	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000946439	1	2021-04-19	2021-04-29	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
57 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intravenous (not otherwise specified)		Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Back pain	v.24.1	
Chills	v.24.1	
Movement disorder	v.24.1	
Pyrexia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000946636	0	2021-04-20	2021-04-20	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
62 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR		0.5 ml			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.24.1	
Fatigue	v.24.1	
Hypoglycaemia	v.24.1	
Pain	v.24.1	
Pyrexia	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000946639	0	2021-04-21	2021-04-21	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
68 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR			Once		
RYBELSUS	Concomitant	Tablets					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	2 Days
Pain in extremity	v.24.1	2 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000946642	0	2021-04-20	2021-04-20	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
70 Years	Male	66 Inch	83 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect				Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	9 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000946645	0	2021-04-20	2021-04-20	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
60 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	0.5 ml	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Feeling hot	v.24.1	
Injection site erythema	v.24.1	
Injection site paraesthesia	v.24.1	
Injection site warmth	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000946874	0	2021-04-21	2021-04-21	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
65 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.5 ml	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Erectile dysfunction	v.24.1	
Vision blurred	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000946877	0	2021-04-21	2021-04-21	Community		Spontaneous	Other health professional

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Herpes zoster	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000946881	0	2021-04-21	2021-04-21	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:		Disability:		Congenital Anomaly:	
Not Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR			Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Adverse event	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000946887	1	2021-04-21	2021-05-10	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
62 Years	Female	67 Inch	185 Pound	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cellulitis	v.24.1	
Feeling hot	v.24.1	
Pain	v.24.1	
Peripheral swelling	v.24.1	
Urticaria	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000946889	0	2021-04-21	2021-04-21	Community		Spontaneous	Pharmacist

Serious report?	Death:		Disability:	Yes	Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	

Patient Information

Age	Gender	Height	Weight	Report Outcome
76 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AMLODIPINE	Concomitant	Tablets					
ATENOLOL TABLETS, BP	Concomitant	Tablets					
CALCIUM	Concomitant	NOT SPECIFIED					
COLESTID	Concomitant	NOT SPECIFIED					
HYDROCHLOROTHIAZIDE	Concomitant	Tablets					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				COVID-19 prophylaxis
PRAMIPEXOLE	Concomitant	NOT SPECIFIED					
TRAZODONE	Concomitant	Tablets					
TYLENOL	Concomitant	NOT SPECIFIED					
VITAMIN D	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Migraine	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000946893	0	2021-04-21	2021-04-21	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
57 Years	Female	65 Inch	134 Pound	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR			Once		COVID-19 prophylaxis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Injection site cellulitis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000946897	0	2021-04-21	2021-04-21	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CRESTOR	Concomitant	Tablets					
CYMBALTA	Concomitant	NOT SPECIFIED					
METFORMIN	Concomitant	Tablets					
OZEMPIC	Concomitant	SOLUTION SUBCUTANEOUS					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		
VITAMIN D	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Angioedema	v.24.1	
Lip swelling	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000946902	0	2021-04-21	2021-04-21	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Paraesthesia	v.24.1	
Paraesthesia oral	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000946910	0	2021-04-21	2021-04-21	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypoaesthesia	v.24.1	
Paraesthesia	v.24.1	
Peripheral coldness	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000947114	0	2021-04-22	2021-04-22	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
61 Years	Female	60 Inch	120 Pound	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Rotator cuff syndrome	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000947126	0	2021-04-22	2021-04-22	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
57 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cellulitis	v.24.1	
Erythema	v.24.1	
Feeling hot	v.24.1	
Fluctuance	v.24.1	
Induration	v.24.1	
Pain	v.24.1	
Swelling	v.24.1	
Tenderness	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000947138	0	2021-04-22	2021-04-22	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
57 Years	Male	171 Centimeter	117 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	1.0 Dosage forms	Once		COVID-19 immunisation
LENALIDOMIDE	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Deep vein thrombosis	v.24.1	8 Days
Dyspnoea	v.24.1	
Pain in extremity	v.24.1	
Peripheral swelling	v.24.1	
Pulmonary embolism	v.24.1	8 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000947161	0	2021-04-22	2021-04-22	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
67 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR			Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Herpes zoster	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000947166	0	2021-04-22	2021-04-22	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
64 Years	Female		64 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Once		
PROMETRIUM	Concomitant	Capsules					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Postmenopausal haemorrhage	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000947167	0	2021-04-22	2021-04-22	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
83 Years	Female			Recovering/resolving

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Herpes zoster	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000947169	0	2021-04-22	2021-04-22	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
59 Years	Female	63 Inch	132 Pound	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.5 ml	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Facial pain	v.24.1	
Fatigue	v.24.1	
Headache	v.24.1	
Lethargy	v.24.1	
Muscle spasms	v.24.1	
Neck pain	v.24.1	
Pain in extremity	v.24.1	
Vaccination site pain	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Vaccination site swelling	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000947170	0	2021-04-22	2021-04-22	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
65 Years	Female	157 Centimeter		Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				COVID-19

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Injection site movement impairment	v.24.1	3 Days
Pain in extremity	v.24.1	3 Days
Wrong technique in product usage process	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000947172	0	2021-04-23	2021-04-23	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
62 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Burning sensation	v.24.1	
Erythema	v.24.1	
Fatigue	v.24.1	
Headache	v.24.1	
Injection site vesicles	v.24.1	
Pain	v.24.1	
Skin discolouration	v.24.1	
Skin irritation	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000947173	0	2021-04-22	2021-04-22	Community	2246196	Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
48 Years	Female	65 Inch	130 Pound	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.5 ml	Once		COVID-19 immunisation
TYLENOL	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Erythema	v.24.1	
Feeling hot	v.24.1	
Rash	v.24.1	
Rash macular	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000947175	0	2021-04-22	2021-04-22	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
36 Years	Female	67 Inch	280 Pound	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	0.5 ml	Once		
FLONASE ALLERGY AQUEOUS NASAL SPRAY	Concomitant	SPRAY, METERED DOSE					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Feeling hot	v.24.1	
Injection site erythema	v.24.1	
Injection site mass	v.24.1	
Injection site pruritus	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Injection site rash	v.24.1	
Injection site warmth	v.24.1	
Pain in extremity	v.24.1	
Pruritus	v.24.1	
Rash	v.24.1	
Rash macular	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000947180	0	2021-04-22	2021-04-22	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
85 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
APALUTAMIDE	Concomitant						
DEGARELIX ACETATE	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR			Once		
PREDNISONE	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Condition aggravated	v.24.1	
Dermatitis exfoliative generalised	v.24.1	
Erythema	v.24.1	
Generalised oedema	v.24.1	
Pain	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Peripheral swelling	v.24.1	
Pruritus	v.24.1	
Skin exfoliation	v.24.1	
Skin weeping	v.24.1	
Stevens-Johnson syndrome	v.24.1	
Sympathetic ophthalmia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000947185	0	2021-04-22	2021-04-22	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
84 Years	Male		80 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CORTISONE	Concomitant	Injection					
KENALOG-40 INJECTION 40MG/ML	Concomitant	SUSPENSION INTRA-ARTICULAR					
LIDOCAINE	Concomitant	Spray (not inhalation)					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Confusional state	v.24.1	6 Days
Fatigue	v.24.1	6 Days
Tremor	v.24.1	6 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000947188	0	2021-04-22	2021-04-22	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
64 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.5 ml	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Feeling hot	v.24.1	
Pain in extremity	v.24.1	
Swelling	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000947193	1	2021-04-22	2021-04-29	Hospital		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
64 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect						
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect						
RIVAROXABAN	Concomitant	Film-coated tablet	Unknown				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Atelectasis	v.24.1	
Chest pain	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.24.1	
Dyspnoea	v.24.1	
Pulmonary embolism	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000947388	0	2021-04-23	2021-04-23	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
32 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	30.0 Microgram	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blister	v.24.1	
Herpes zoster	v.24.1	
Hypoaesthesia	v.24.1	
Oral herpes	v.24.1	
Pain of skin	v.24.1	
Paraesthesia	v.24.1	
Pruritus	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Rash erythematous	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000947392	0	2021-04-23	2021-04-23	Hospital		Spontaneous	Physician

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
73 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACTIVASE RT-PA	Suspect	LIQUID INTRAVENOUS	Intravenous bolus	100.0 Milligram	Once		Cerebrovascular accident
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Parenteral	1.0 Dosage forms	Once		COVID-19 immunisation
RAMIPRIL	Concomitant	Tablets					
SYNTHROID	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cerebral infarction	v.24.1	
Cerebral mass effect	v.24.1	
Cerebrovascular accident	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dysarthria	v.24.1	
Facial paralysis	v.24.1	
Haemorrhagic transformation stroke	v.24.1	
Hemiplegia	v.24.1	
Intraventricular haemorrhage	v.24.1	
Neurologic neglect syndrome	v.24.1	
Subarachnoid haemorrhage	v.24.1	
Tongue paralysis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information

***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000947393	0	2021-04-23	2021-04-23	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
47 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ESCITALOPRAM	Concomitant	Tablets					
INDAPAMIDE	Concomitant	Tablets					
MINESTRIN 1/20 21	Concomitant	Tablets					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Once		COVID-19 immunisation
ROSUVASTATIN	Concomitant	Tablets	Unknown				
SYNTHROID	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Deep vein thrombosis	v.24.1	
Pain in extremity	v.24.1	
Swelling	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000947394	0	2021-04-23	2021-04-23	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
69 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain upper	v.24.1	
Arthralgia	v.24.1	
Burning sensation	v.24.1	
Fatigue	v.24.1	
Headache	v.24.1	
Hypoaesthesia	v.24.1	
Pain	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Paraesthesia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000947395	0	2021-04-23	2021-04-23	Hospital		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
58 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR			Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Ataxia	v.24.1	
Balance disorder	v.24.1	
Cerebellar infarction	v.24.1	
Decreased appetite	v.24.1	
Dizziness	v.24.1	
Dysstasia	v.24.1	
Extensor plantar response	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Gait inability	v.24.1	
Hyporeflexia	v.24.1	
Nausea	v.24.1	
Sitting disability	v.24.1	
Upper motor neurone lesion	v.24.1	
Vertebral artery dissection	v.24.1	
Vertebral artery occlusion	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000947396	0	2021-04-23	2021-04-23	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
71 Years	Female	59 Inch	110 Pound	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASPIRIN	Concomitant	NOT SPECIFIED					
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	0.5 ml	Once		COVID-19 immunisation
ROSUVASTATIN	Concomitant	Tablets	Unknown				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.24.1	5 Days
Rash	v.24.1	5 Days
Rash erythematous	v.24.1	5 Days
Rash papular	v.24.1	5 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000947398	0	2021-04-23	2021-04-23	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
40 Years	Female	157 Centimeter	136 Pound	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Rash	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000947400	0	2021-04-23	2021-04-23	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
66 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.5 ml	Once		Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Ear pain	v.24.1	
Fatigue	v.24.1	
Headache	v.24.1	
Myalgia	v.24.1	
Nausea	v.24.1	
Oropharyngeal pain	v.24.1	
Throat irritation	v.24.1	2 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000947402	0	2021-04-23	2021-04-23	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
29 Years	Female	68 Inch	148 Pound	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular		Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	
Injection site irritation	v.24.1	
Injection site pruritus	v.24.1	
Pain in extremity	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000947403	0	2021-04-23	2021-04-23	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
83 Years	Female	165 Centimeter	66 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR			Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Tinea pedis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000947405	0	2021-04-23	2021-04-23	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
40 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR			Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Dyspnoea	v.24.1	
Gait disturbance	v.24.1	
Headache	v.24.1	
Loss of personal independence in daily activities	v.24.1	
Pyrexia	v.24.1	
Vision blurred	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000947407	0	2021-04-25	2021-04-25	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
70 Years	Female	152 Centimeter	57 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Fatigue	v.24.1	
Herpes zoster	v.24.1	
Pain in extremity	v.24.1	
Pruritus	v.24.1	
Rash	v.24.1	
Rash vesicular	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000947409	0	2021-04-25	2021-04-25	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
30 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	
Hypoaesthesia	v.24.1	
Nausea	v.24.1	
Pain in extremity	v.24.1	
Skin discolouration	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000947411	1	2021-04-25	2021-05-08	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
66 Years	Female	160 Centimeter	60 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AMOXICILLIN	Concomitant	NOT SPECIFIED					
AVAMYS	Concomitant	SPRAY, METERED DOSE					
BETADERM CRM 0.05%	Concomitant	Cream					
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect			0.5 ml	Once	7.0 Days	
JUBLIA	Concomitant	SOLUTION TOPICAL					
ZOVIRAX	Concomitant	Tablets					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Injection site erythema	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Injection site warmth	v.24.1	
Lymphadenopathy	v.24.1	
Pruritus	v.24.1	
Rash papular	v.24.1	
Urticaria	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000947416	0	2021-04-23	2021-04-23	Community		Spontaneous	Physician

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
74 Years	Male	170 Centimeter	82 Kilogram	Recovering/resolving

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CRESTOR	Concomitant	Tablets					
DYAZIDE TAB	Concomitant	Tablets					
JANUMET	Concomitant	NOT SPECIFIED	Unknown				
LORAZEPAM	Concomitant	NOT SPECIFIED					
NORVASC	Concomitant	Tablets					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					COVID-19 immunisation
RABEPRAZOLE	Concomitant	NOT SPECIFIED					
TRAZODONE	Concomitant	Tablets					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dermatitis allergic	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Rash maculo-papular	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000947418	0	2021-04-25	2021-04-25	Hospital		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
65 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ADVAIR 250 DISKUS	Concomitant	NOT SPECIFIED					
ALLOPURINOL	Concomitant	Tablets					
AMLODIPINE	Concomitant	Tablets					
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR			Once		
BISOPROLOL	Concomitant	Tablets					
CANDESARTAN	Concomitant						
CHLORTHALIDONE	Concomitant	Tablets					
ELIQUIS	Concomitant	Tablets					
FINASTERIDE	Concomitant	Tablets					
FUROSEMIDE	Concomitant	Tablets					
IRON	Concomitant						

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
LANTUS	Concomitant	SOLUTION SUBCUTANEOUS					
LORAZEPAM	Concomitant	NOT SPECIFIED					
MONTELUKAST	Concomitant	NOT SPECIFIED					
MULTIVITAMIN	Concomitant	Tablet					
NOVORAPID	Concomitant	SOLUTION SUBCUTANEOUS					
OMEPRAZOLE	Concomitant	CAPSULE, DELAYED RELEASE					
PREGABALIN	Concomitant	Capsules					
ROSUVASTATIN	Concomitant	Tablets	Unknown				
TAMSULOSIN	Concomitant	NOT SPECIFIED					
TEMAZEPAM	Concomitant	Capsules					
VENTOLIN	Concomitant	NOT SPECIFIED	Inhalation				
VITAMIN B COMPLEX	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest discomfort	v.24.1	
Chills	v.24.1	
Confusional state	v.24.1	
Diarrhoea	v.24.1	
Dyspnoea	v.24.1	
Malaise	v.24.1	
Pyrexia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000947420	0	2021-04-24	2021-04-24	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
67 Years	Female	152 Centimeter	73 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AMLODIPINE	Concomitant	Tablets					
HYDROCHLOROTHIAZIDE	Concomitant	Tablets					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Once		COVID-19 immunisation
RAMIPRIL	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Rash pruritic	v.24.1	8 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000947422	0	2021-04-25	2021-04-25	Hospital		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
70 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		COVID-19 prophylaxis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cerebrovascular accident	v.24.1	
Nausea	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000947578	0	2021-04-26	2021-04-26	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
73 Years	Male	173 Centimeter	79 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect						
TWYNSTA	Concomitant	Tablets					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Muscle strain	v.24.1	
Swelling	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000947581	0	2021-04-26	2021-04-26	Community		Spontaneous	Physician

Serious report?	Death: Yes	Disability:	Congenital Anomaly:
Serious	Life Threatening:	Hospitalization:	Other Medically Important Conditions:

Patient Information

Age	Gender	Height	Weight	Report Outcome
72 Years	Female	63 Inch	140 Pound	Fatal

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
LOSARTAN	Concomitant	Tablets					
NORVASC	Concomitant	Tablets					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Death	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000947597	0	2021-04-26	2021-04-26	Hospital		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
57 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Subcutaneous				COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.24.1	
Dyspnoea	v.24.1	
Intracranial aneurysm	v.24.1	
Oedema peripheral	v.24.1	
Pain in extremity	v.24.1	
Pulmonary embolism	v.24.1	
Pulmonary infarction	v.24.1	
Thrombocytopenia	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000947601	0	2021-04-26	2021-04-26	Community		Spontaneous	Physician

Serious report?	Death:	Yes	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
48 Years	Female	67 Inch	80 Kilogram	Fatal

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular		Once		
FLOVENT HFA	Concomitant	METERED-DOSE (AEROSOL)					
FLURAZEPAM HYDROCHLORIDE	Concomitant	Capsules					
JAMP DULOXETINE CAPSULES	Concomitant	CAPSULE, DELAYED RELEASE					
LEVOTHYROXINE	Concomitant	Tablets					
MELATONIN	Concomitant	NOT SPECIFIED					
METHOTRIMEPRAZINE	Concomitant	NOT SPECIFIED					
ONDANSETRON	Concomitant	Tablets					
PMS-RABEPRAZOLE EC	Concomitant	TABLET (ENTERIC-COATED)					

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PREGABALIN	Concomitant	Capsules					
RANITIDINE	Concomitant	Tablets					
SALBUTAMOL	Concomitant	INHALATION					
TEVA-FENTANYL	Concomitant	PATCH					
TEVA-NABILONE	Concomitant	Capsules					
TRAZODONE	Concomitant	Tablets					
[SANDOZ-DICLOFENAC]	Concomitant	Suppository					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.24.1	
Nausea	v.24.1	
Somnolence	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000947602	0	2021-04-26	2021-04-26	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
68 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Feeling cold	v.24.1	2 Days
Influenza like illness	v.24.1	2 Days
Night sweats	v.24.1	2 Days
Nightmare	v.24.1	2 Days
Pain	v.24.1	2 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000947604	0	2021-04-26	2021-04-26	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
68 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR			Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.24.1	
Diarrhoea	v.24.1	
Dizziness	v.24.1	
Fatigue	v.24.1	
Flushing	v.24.1	
Headache	v.24.1	
Hypoaesthesia	v.24.1	
Injection site erythema	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Injection site pain	v.24.1	
Injection site swelling	v.24.1	
Nausea	v.24.1	
Paraesthesia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000947606	0	2021-04-26	2021-04-26	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
51 Years	Female	60 Inch	100 Pound	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	0.5 ml	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Injection site reaction	v.24.1	
Rash	v.24.1	
Urticaria	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000947609	0	2021-04-26	2021-04-26	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
25 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CYCLOBENZAPRINE	Concomitant	NOT SPECIFIED	Unknown				
DEPO-PROVERA STERILE AQUEOUS SUSPENSION	Concomitant	SUSPENSION INTRAMUSCULAR					
DEXILANT	Concomitant	CAPSULE, DELAYED RELEASE					
NUCYNTA	Concomitant	Tablets					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Angina pectoris	v.24.1	
Asthenia	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.24.1	
Dysgeusia	v.24.1	
Dyspnoea	v.24.1	
Eye pain	v.24.1	
Facial pain	v.24.1	
Hypoaesthesia	v.24.1	
Oropharyngeal pain	v.24.1	
Pain in jaw	v.24.1	
Salivary gland enlargement	v.24.1	
Somnolence	v.24.1	
Swollen tongue	v.24.1	
Tremor	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000947610	0	2021-04-26	2021-04-26	Hospital		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
57 Years				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR		0.5 ml	Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.24.1	
Headache	v.24.1	
Malaise	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000947614	0	2021-04-26	2021-04-26	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
57 Years	Female	163 Centimeter	65 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AMLODIPINE	Concomitant	Tablets					
MYCOPHENOLIC ACID	Concomitant	NOT SPECIFIED					
PERINDOPRIL	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	3.0 ml			COVID-19 immunisation
PREDNISONE	Concomitant	NOT SPECIFIED					
PROGRAF	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Appendicectomy	v.24.1	
Appendicitis	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000947793	0	2021-04-27	2021-04-27	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
55 Years	Female			Recovering/resolving

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pain in extremity	v.24.1	17 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000947794	0	2021-04-27	2021-04-27	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
72 Years	Female	67 Inch	150 Pound	Recovering/resolving

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Herpes zoster	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000947800	0	2021-04-27	2021-04-27	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Duplicate	000947804

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect						
METFORMIN	Concomitant						
METHOTREXATE	Concomitant	NOT SPECIFIED	Intrathecal				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Herpes zoster	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000947802	0	2021-04-27	2021-04-27	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect				Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Brain injury	v.24.1	
Cerebral thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000947803	0	2021-04-27	2021-04-27	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
55 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR			Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.24.1	
Night sweats	v.24.1	
Tinnitus	v.24.1	
Vertigo	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000947806	0	2021-04-27	2021-04-27	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
52 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	30.0 Microgram	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pruritus	v.24.1	
Rash	v.24.1	
Urticaria	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000947809	0	2021-04-27	2021-04-27	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
78 Years	Female	20 Centimeter	66 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CBD OIL	Concomitant						
CRANBERRY EXTRACT 1132 MG (HERBAL EQUIV.)	Concomitant	Capsules					
FLEXERIL /00428402/	Concomitant						
HYDROCHLOROTHIAZIDE	Concomitant	Tablets					
MAGNESIUM	Concomitant	Capsule					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		COVID-19 prophylaxis
PREMARIN	Concomitant	NOT SPECIFIED					
SUPER B COMPLEX	Concomitant	Capsule					
TECTA (PANTOPRAZOLE MAGNESIUM)	Concomitant	Tablets					

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
TYLENOL WITH CODEINE #3	Concomitant						
VITAMIN B12	Concomitant	NOT SPECIFIED					
VITAMIN D3 1000 IU TABLETS	Concomitant	Tablets					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.24.1	
Taste disorder	v.24.1	
Vertigo	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000947810	0	2021-04-28	2021-04-28	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
51 Years	Female	180 Centimeter	77 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	1.0 Dosage forms	Once		COVID-19 immunisation
CYMBALTA	Concomitant	NOT SPECIFIED					
HYDROMORPHONE	Concomitant	NOT SPECIFIED					
IMOVANE	Concomitant	Tablets					
THYROXINE	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Back pain	v.24.1	
Breast pain	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Injection site bruising	v.24.1	
Injection site pain	v.24.1	
Muscle spasms	v.24.1	
Postmenopausal haemorrhage	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000947991	0	2021-04-28	2021-04-28	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
55 Years	Male	73 Inch	198 Pound	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular		Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bone pain	v.24.1	
Malaise	v.24.1	
Myalgia	v.24.1	
Pain in extremity	v.24.1	
Paraesthesia	v.24.1	
Peripheral swelling	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Thrombophlebitis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000947992	0	2021-04-28	2021-04-28	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
30 Years	Female	36 Inch		Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Feeling hot	v.24.1	5 Days
Injection site erythema	v.24.1	5 Days
Injection site inflammation	v.24.1	5 Days
Injection site pruritus	v.24.1	5 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000947994	0	2021-04-28	2021-04-28	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
49 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	30.0 Microgram	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Ear discomfort	v.24.1	
Head discomfort	v.24.1	
Herpes zoster	v.24.1	
Insomnia	v.24.1	
Malaise	v.24.1	
Pain	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pain of skin	v.24.1	
Rash	v.24.1	
Rash pruritic	v.24.1	
Rash vesicular	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000947996	0	2021-04-28	2021-04-28	Hospital		Spontaneous	Physician

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
46 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				COVID-19 prophylaxis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pulmonary embolism	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000947997	0	2021-04-28	2021-04-28	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
71 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	0.5 ml	Once		COVID-19 prophylaxis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Rash erythematous	v.24.1	
Rash pruritic	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000947998	0	2021-04-28	2021-04-28	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
80 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	0.5 ml	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Erythema	v.24.1	
Feeling hot	v.24.1	
Rash	v.24.1	
Swelling	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000948001	0	2021-04-28	2021-04-28	Community		Spontaneous	Nurse

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
64 Years	Female	64 Inch	167 Pound	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Papule	v.24.1	
Pruritus	v.24.1	
Urticaria	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000948003	0	2021-04-28	2021-04-28	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
41 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.24.1	
Dyspnoea	v.24.1	
Urticaria	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000948005	0	2021-04-28	2021-04-28	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
51 Years	Female	63 Inch	189 Pound	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	2 Days
Headache	v.24.1	2 Days
Injection site pain	v.24.1	2 Days
Musculoskeletal stiffness	v.24.1	2 Days
Pain in extremity	v.24.1	2 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000948006	1	2021-04-28	2021-05-13	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
56 Years	Female	66 Inch		Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular		Once		COVID-19 immunisation
ESTROGENS	Concomitant	NOT SPECIFIED					
FISH OIL	Concomitant	NOT SPECIFIED					
METAMUCIL	Concomitant	NOT SPECIFIED					
MULTIVITAMINS WITH MINERALS	Concomitant	NOT SPECIFIED					
PROBIOTIC	Concomitant	NOT SPECIFIED					
RESTORALAX	Concomitant	POWDER FOR SOLUTION ORAL					
VITAMIN B12	Concomitant	Tablets					
VITAMIN D	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anxiety	v.24.1	3 Days
Arthralgia	v.24.1	3 Days
Asthenia	v.24.1	3 Days
Back pain	v.24.1	3 Days
Concomitant disease aggravated	v.24.1	
Decreased appetite	v.24.1	3 Days
Dizziness	v.24.1	3 Days
Fatigue	v.24.1	3 Days
Fibromyalgia	v.24.1	
Hyperhidrosis	v.24.1	3 Days
Myalgia	v.24.1	3 Days
Oropharyngeal pain	v.24.1	3 Days
Pain	v.24.1	3 Days
Pain in extremity	v.24.1	3 Days
Pruritus	v.24.1	3 Days
Pyrexia	v.24.1	3 Days
Rhinorrhoea	v.24.1	3 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000948012	0	2021-04-28	2021-04-28	Hospital		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
68 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ALENDRONATE	Concomitant	Tablets					
CALCIUM	Concomitant	NOT SPECIFIED					
CYANOCOBALAMIN	Concomitant	NOT SPECIFIED					
DULOXETINE	Concomitant	NOT SPECIFIED	Unknown				
EPIPEN 0.3MG	Concomitant	NOT SPECIFIED					
FOLIC ACID	Concomitant	NOT SPECIFIED					
GABAPENTIN	Concomitant	NOT SPECIFIED					
METFORMIN	Concomitant	Tablets					
METHOTREXATE	Concomitant	NOT SPECIFIED					
OZEMPIC	Concomitant	SOLUTION SUBCUTANEOUS					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	30.0 Microgram	Once		COVID-19 immunisation

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					COVID-19 immunisation
PRAMIPEXOLE	Concomitant	NOT SPECIFIED					
SODIUM CHLORIDE INJECTION USP SINGLE-USE VIAL	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular		Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dysphagia	v.24.1	
Dysphonia	v.24.1	1 Days
Dyspnoea	v.24.1	
Endotracheal intubation	v.24.1	
Malaise	v.24.1	
Stridor	v.24.1	
Swollen tongue	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000948177	0	2021-04-29	2021-04-29	Community		Spontaneous	Nurse

Serious report?	Death:		Disability:		Congenital Anomaly:	
Not Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female	167 Centimeter	191 Pound	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml			COVID-19 immunisation
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Chills	v.24.1	
Fatigue	v.24.1	
Influenza like illness	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Myalgia	v.24.1	
Pyrexia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000948179	0	2021-04-29	2021-04-29	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Itching scar	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000948181	0	2021-04-29	2021-04-29	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
69 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal discomfort	v.24.1	
Apathy	v.24.1	
Asthenia	v.24.1	
Bradykinesia	v.24.1	
Burning sensation	v.24.1	
Diarrhoea	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Disorientation	v.24.1	
Erythema	v.24.1	
Eye pain	v.24.1	
Eye swelling	v.24.1	
Fatigue	v.24.1	
Feeling abnormal	v.24.1	
Herpes zoster	v.24.1	
Malaise	v.24.1	
Memory impairment	v.24.1	
Mental impairment	v.24.1	
Nodule	v.24.1	
Ocular hyperaemia	v.24.1	
Pain	v.24.1	
Pain in extremity	v.24.1	
Pain of skin	v.24.1	
Poor quality sleep	v.24.1	
Pruritus	v.24.1	
Pustule	v.24.1	
Pyrexia	v.24.1	
Rash erythematous	v.24.1	
Skin swelling	v.24.1	
Sleep deficit	v.24.1	
Urticaria	v.24.1	
Visual impairment	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000948182	0	2021-04-29	2021-04-29	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
62 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.5 ml			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.24.1	
Pain	v.24.1	
Pyrexia	v.24.1	
Rash	v.24.1	
Rash pruritic	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000948196	0	2021-04-29	2021-04-29	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
73 Years	Male	170 Centimeter	67 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASA	Concomitant	NOT SPECIFIED	Unknown				
FISH OIL	Concomitant	NOT SPECIFIED					
LUTEIN	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	30.0 Microgram	Once		COVID-19 immunisation
RAMIPRIL	Concomitant	NOT SPECIFIED					
VITAMIN B12	Concomitant	NOT SPECIFIED					
VITAMIN D	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Contusion	v.24.1	
Immune thrombocytopenia	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Platelet count decreased	v.24.1	
Platelet transfusion	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000948197	0	2021-04-29	2021-04-29	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
63 Years	Female		170 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abnormal dreams	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000948198	0	2021-04-29	2021-04-29	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
33 Years	Female	163 Centimeter	125 Pound	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	8 Days
Headache	v.24.1	8 Days
Nausea	v.24.1	8 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000948199	0	2021-04-29	2021-04-29	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
74 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anxiety	v.24.1	
Blood pressure increased	v.24.1	
Chest pain	v.24.1	
Heart rate increased	v.24.1	
Increased appetite	v.24.1	
Pain in extremity	v.24.1	
Palpitations	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Sleep disorder	v.24.1	
Tremor	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000948200	0	2021-04-29	2021-04-29	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
40 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 8 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.5 ml	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	
Headache	v.24.1	
Nausea	v.24.1	
Pyrexia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000948203	0	2021-04-29	2021-04-29	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
51 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.5 ml			COVID-19 immunisation
IBUPROFEN	Concomitant	NOT SPECIFIED					
IRON	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Influenza like illness	v.24.1	
Macule	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000948204	0	2021-04-29	2021-04-29	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
55 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.5 ml			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.24.1	6 Days
Limb discomfort	v.24.1	6 Days
Pain	v.24.1	6 Days
Paraesthesia	v.24.1	6 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000948205	0	2021-04-29	2021-04-29	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female	170 Centimeter	103 Pound	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
APO CIMETIDINE TAB 200MG	Concomitant	Tablets					
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR					
BACLOFEN-10 - TAB	Concomitant	Tablets					
EPINEPHRINE	Concomitant	NOT SPECIFIED					
EZETROL	Concomitant	Tablets					
FUROSEMIDE	Concomitant	NOT SPECIFIED					
GABAPENTIN	Concomitant	Capsules					
JANUVIA	Concomitant	Tablets					
LAMISIL [TERBINAFINE HYDROCHLORIDE]	Concomitant	NOT SPECIFIED					

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
LANTUS	Concomitant	SOLUTION SUBCUTANEOUS					
LODALIS	Concomitant	POWDER FOR SUSPENSION ORAL					
LOMOTIL	Concomitant	Tablets					
MONTELUKAST	Concomitant	Tablets					
NOVORAPID	Concomitant	SOLUTION SUBCUTANEOUS					
PERINDOPRIL ERBUMINE	Concomitant	Tablets					
ROSUVASTATIN	Concomitant	Tablets					
SYMBICORT TURBUHALER	Concomitant	Powder					
TECTA (PANTOPRAZOLE MAGNESIUM)	Concomitant	Tablets					
TOPIRAMATE	Concomitant	NOT SPECIFIED					
VENTOLIN INHALER 100MCG/AEM	Concomitant	METERED-DOSE (AEROSOL)					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Erythema	v.24.1	
Fatigue	v.24.1	
Pruritus	v.24.1	
Pyrexia	v.24.1	
Swelling	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000948400	0	2021-04-30	2021-04-30	Hospital		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
57 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular		Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anti-platelet antibody	v.24.1	
Deep vein thrombosis	v.24.1	7 Days
Fibrin D dimer increased	v.24.1	
Headache	v.24.1	
Immune thrombocytopenia	v.24.1	7 Days
Oedema peripheral	v.24.1	
Platelet count decreased	v.24.1	
Pulmonary embolism	v.24.1	7 Days

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pulmonary infarction	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000948407	0	2021-04-30	2021-04-30	Hospital		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
47 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CHOLESTYRAMINE	Concomitant	NOT SPECIFIED					
HYDROMORPHONE	Concomitant	NOT SPECIFIED					
HYDROXYZINE	Concomitant	NOT SPECIFIED					
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular		Once		COVID-19 immunisation
ROSUVASTATIN	Concomitant	Tablets	Unknown				
TACROLIMUS	Concomitant	Capsules					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.24.1	1 Days
Angioedema	v.24.1	
Aphasia	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cerebrovascular accident	v.24.1	
Hemiparesis	v.24.1	
Rash	v.24.1	
Upper motor neurone lesion	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000948409	0	2021-04-30	2021-04-30	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
56 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BREO ELLIPTA	Concomitant	INHALATION	Unknown				
CELEXA	Concomitant	Tablets					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		COVID-19 immunisation
PREVACID	Concomitant	NOT SPECIFIED					
SPIRIVA	Concomitant	NOT SPECIFIED	Unknown				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Burning sensation	v.24.1	
Fatigue	v.24.1	
Herpes zoster	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pruritus	v.24.1	
Rash	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000948415	0	2021-04-30	2021-04-30	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
58 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.5 ml	Once		COVID-19 prophylaxis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	
Influenza like illness	v.24.1	
Myalgia	v.24.1	
Nausea	v.24.1	
Pruritus	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000948418	0	2021-04-30	2021-04-30	Community		Spontaneous	Nurse

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
40 Years	Female	64 Inch	117 Pound	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	0.5 ml	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Diarrhoea	v.24.1	
Dizziness	v.24.1	
Fatigue	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000948419	0	2021-04-30	2021-04-30	Community		Spontaneous	Physician

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
60 Years	Female	173 Centimeter	73 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.5 ml			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Herpes zoster	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000948420	0	2021-04-30	2021-04-30	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR			Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Rash	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000948421	0	2021-04-30	2021-04-30	Hospital		Spontaneous	Physician

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
53 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bell's palsy	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000948422	0	2021-04-30	2021-04-30	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
53 Years	Female	63 Inch	165 Pound	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR		0.5 ml	Once		Prophylaxis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dry mouth	v.24.1	
Dysphagia	v.24.1	
Muscle tightness	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000948423	0	2021-04-30	2021-04-30	Community		Spontaneous	Physician

Serious report?	Death:		Disability:	No	Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
56 Years	Female		60 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR					Prophylaxis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypothyroidism	v.24.1	
Tachycardia	v.24.1	
Weight decreased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000948425	0	2021-04-30	2021-04-30	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
70 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Infection	v.24.1	
Injection site swelling	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000948426	0	2021-04-30	2021-04-30	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
57 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR		0.5 ml			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Influenza like illness	v.24.1	
Tenderness	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000954666	1	2021-04-19	2021-06-16	MAH	803972	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male	167 Centimeter	87 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BASAGLAR KWIKPEN - 60 UNITS PER INJECTION DELIVERY	Concomitant	SOLUTION SUBCUTANEOUS					
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect				Once		COVID-19 immunisation
NOVORAPID 3ML PENFILL CARTRIDGE	Suspect	SOLUTION SUBCUTANEOUS	Unknown				Type 1 diabetes mellitus
NOVORAPID 3ML PENFILL CARTRIDGE	Suspect	SOLUTION SUBCUTANEOUS	Unknown				Type 1 diabetes mellitus
NOVORAPID 3ML PENFILL CARTRIDGE	Suspect	SOLUTION SUBCUTANEOUS	Unknown	17.0 IU (International Unit)	3 every 1 Days		Type 1 diabetes mellitus

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood glucose increased	v.24.1	
Drug interaction	v.24.1	
Ketoacidosis	v.24.1	
Product quality issue	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000983744	0	2021-04-30	2021-04-30	Hospital		Spontaneous	Other health professional

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
67 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect						COVID-19 immunisation
FINASTERIDE	Concomitant	Tablets					
FLOMAX	Suspect	CAPSULE, SUSTAINED-RELEASE	Unknown				Prostatomegaly
HUMALOG	Concomitant	Injection					
INSULIN GLARGINE	Concomitant	SOLUTION SUBCUTANEOUS					
JARDIANCE	Concomitant	Tablets					
LOPERAMIDE	Concomitant						
METFORMIN	Concomitant	Tablets					
RAMIPRIL	Concomitant	Capsules	Unknown				
SIMVASTATIN	Concomitant	Tablets					

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
TAMSULOSIN SODIUM SANDOZ	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypotension	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03715898	2	2021-01-06	2021-04-29	MAH	2020520236	Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
5 Decade	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Months	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03719041	2	2021-01-07	2021-03-01	MAH	2021005203	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
39 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03721753	1	2021-01-08	2021-01-08	MAH	2021000386	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
40 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypersensitivity	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03722149	4	2021-01-08	2021-08-18	MAH	2021003110	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
42 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain upper	v.24.1	5 Days
COVID-19	v.24.1	
Pain	v.24.1	3 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information

***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03724997	1	2021-01-11	2021-01-14	MAH	2021012878	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
47 Years	Female		59 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Feeling cold	v.24.1	1 Months
Hypertension	v.24.1	1 Months
Hypoaesthesia	v.24.1	1 Months
Stress	v.24.1	1 Months
Tongue disorder	v.24.1	1 Months

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03730662	0	2021-01-13	2021-01-13	MAH	2021010566	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Drug ineffective	v.24.1	
SARS-CoV-2 test positive	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03730867	3	2021-01-13	2021-03-05	MAH	2021018220	Spontaneous	Consumer/other non health professional

Serious report?	Death:	Disability:	Congenital Anomaly:
Serious	Yes	No	No
	Life Threatening: No	**Hospitalization:** No	**Other Medically Important Conditions:** Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
90 Years	Male			Fatal

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.24.1	
Drug ineffective	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03733981	1	2021-01-14	2021-01-18	MAH	2021017540	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
35 Years	Female	165 Centimeter	80 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Angioedema	v.24.1	
Off label use	v.24.1	
Product use issue	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03736609	2	2021-01-15	2021-02-08	MAH	2021014380	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
47 Years	Female	166 Centimeter	61 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.24.1	
Arthralgia	v.24.1	
Erythema	v.24.1	
Face oedema	v.24.1	
Fatigue	v.24.1	
Flushing	v.24.1	
Hypertension	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Myalgia	v.24.1	
Paraesthesia	v.24.1	
Pharyngeal swelling	v.24.1	
Pruritus	v.24.1	
Swollen tongue	v.24.1	
Tachycardia	v.24.1	
Vaccination site pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03736969	2	2021-01-15	2021-05-05	MAH	2021021144	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Off label use	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03739083	2	2021-01-18	2021-02-08	MAH	2021017705	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
90 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Agitation	v.24.1	
Cellulitis	v.24.1	
Deafness	v.24.1	
Decreased appetite	v.24.1	
Herpes zoster disseminated	v.24.1	
Lethargy	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Lymphadenopathy	v.24.1	
Rash macular	v.24.1	
Skin injury	v.24.1	
Somnolence	v.24.1	
Varicella	v.24.1	
Vital functions abnormal	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03739105	1	2021-01-18	2021-01-22	MAH	2021021274	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
41 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BUPROPION	Concomitant		Oral	150.0 Milligram	1 every 1 Days		Depression
IVERMECTIN	Concomitant		Topical		As required		Rosacea
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
VITAMIN D [COLECALCIFEROL]	Concomitant			1000.0 IU (International Unit)	1 every 1 Days		Vitamin supplementation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anxiety	v.24.1	
Asthenia	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.24.1	
Fear	v.24.1	
Presyncope	v.24.1	
Tachycardia	v.24.1	
Tachypnoea	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03739818	1	2021-01-18	2021-05-04	MAH	2021026056	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
37 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ESCITALOPRAM OXALATE	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
SYNTHROID	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.24.1	
Headache	v.24.1	
Malaise	v.24.1	
Syncope	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03747708	0	2021-01-21	2021-01-21	MAH	2021026427	Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.24.1	
Drug ineffective	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03753604	1	2021-01-22	2021-04-01	MAH	2021033493	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
27 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest discomfort	v.24.1	
Chest pain	v.24.1	
Fatigue	v.24.1	1 Days
Headache	v.24.1	1 Days
Lung disorder	v.24.1	
Myalgia	v.24.1	1 Days

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pulmonary pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03753890	1	2021-01-22	2021-02-02	MAH	2021034163	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
52 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.24.1	1 Months
Dyspnoea	v.24.1	1 Months
Hypoaesthesia oral	v.24.1	1 Months
Hypotension	v.24.1	1 Months
Lip swelling	v.24.1	1 Months
Mouth swelling	v.24.1	1 Months
Throat tightness	v.24.1	1 Months

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Tremor	v.24.1	1 Months

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03757123	8	2021-01-25	2021-07-13	MAH	MYERS SQUIBB COMPANY	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
70 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CALCIUM	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication
COVID-19 VACCINE	Suspect		Unknown				COVID-19 immunisation
DESOXIMETASONE	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication
HYDROXYCHLOROQUINE SULFATE	Concomitant		Unknown				Product used for unknown indication
ORENCIA	Suspect		Intravenous (not otherwise specified)	750.0 Milligram	1 every 4 Weeks	112.0 Days	Rheumatoid arthritis

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
RISEDRONATE SODIUM	Concomitant		Unknown				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood pressure systolic increased	v.24.1	
Carpal tunnel syndrome	v.24.1	
Drug ineffective	v.24.1	
Feeling abnormal	v.24.1	
Mouth ulceration	v.24.1	
Myalgia	v.24.1	
Therapeutic response decreased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03758996	5	2021-01-26	2021-05-11	MAH	2021SA018711	Study	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
62 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETAMINOPHEN	Concomitant	NOT SPECIFIED	Oral	975.0 Milligram			Premedication
ADVAIR	Concomitant		Unknown	250.0 Microgram	1 every 12 Hours		
ADVAIR	Concomitant	NOT SPECIFIED	Unknown	250.0 Microgram	1 every 12 Hours		
AMIODARONE	Concomitant	Tablet	Unknown	200.0 Milligram	1 every 12 Hours	3.0 Weeks	
ANASTROZOLE	Concomitant		Oral	1.0 Milligram			
ATORVASTATIN	Concomitant	Tablets	Oral	40.0 Milligram			
ATORVASTATIN	Concomitant		Oral	40.0 Milligram			
CETIRIZINE	Concomitant		Unknown	20.0 Milligram			
COVID-19 VACCINE	Suspect		Unknown				COVID-19 immunisation

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
DILTIAZEM	Concomitant		Oral	240.0 Milligram			
FABRAZYME	Suspect	POWDER FOR SOLUTION INTRAVENOUS	Intravenous drip	60.0 Milligram	1 every 2 Weeks		Fabry's disease
POTASSIUM	Concomitant	NOT SPECIFIED	Unknown				
POTASSIUM	Concomitant		Unknown				
POTASSIUM	Concomitant		Unknown				
POTASSIUM	Concomitant		Unknown				
ZOPICLONE	Concomitant	Tablets	Oral	7.5 Milligram	1 every 1 Days		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arrhythmia	v.24.1	
Atrial fibrillation	v.24.1	
Atrial fibrillation	v.24.1	
Dyspnoea	v.24.1	
Fatigue	v.24.1	
Heart rate increased	v.24.1	
Pyrexia	v.24.1	1 Days
Rales	v.24.1	
Sinus rhythm	v.24.1	
Sleep disorder	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03759500	0	2021-01-26	2021-01-26	MAH	2021040225	Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.24.1	
Drug ineffective	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03760112	0	2021-01-26	2021-01-26	MAH	2021034585	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
45 Years	Female	132 Centimeter	86 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CLONAZEPAM	Concomitant	Tablets			every 1 Days		Insomnia, Anxiety
IRON	Concomitant	Tablet		35.0 Milligram	every 1 Days		Anaemia
LYRICA	Concomitant	Capsules		30.0 Milligram	every 1 Days		Fibromyalgia
MAGNESIUM	Concomitant	NOT SPECIFIED		1500.0 Milligram	every 1 Days		Supplementation therapy
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
TEVA-DULOXETINE	Concomitant	NOT SPECIFIED		60.0 Milligram	every 1 Days		Depression
TYLENOL	Concomitant	Tablet					Rheumatoid arthritis, Fibromyalgia

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
TYLENOL	Concomitant	NOT SPECIFIED			3 every 1 Days		Rheumatoid arthritis, Fibromyalgia

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Chills	v.24.1	
Ear discomfort	v.24.1	
Fatigue	v.24.1	
Feeling cold	v.24.1	
Fibromyalgia	v.24.1	
Influenza like illness	v.24.1	
Rheumatoid arthritis	v.24.1	
Throat irritation	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03765443	1	2021-01-28	2021-02-03	MAH	2021034535	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
56 Years	Female	13 Centimeter	57 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
TRAZODONE	Concomitant		Unknown				Insomnia

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	
Headache	v.24.1	
Myalgia	v.24.1	
Pain in extremity	v.24.1	
Pyrexia	v.24.1	3 Days

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Tachycardia	v.24.1	
Vaccination site pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03769592	0	2021-01-29	2021-01-29	MAH	2021040144	Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
39 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hyperhidrosis	v.24.1	
Hypotension	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03772703	1	2021-02-01	2021-02-08	MAH	2021081194	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
42 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Meningitis aseptic	v.24.1	
Pneumonia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03777332	2	2021-02-02	2021-02-23	MAH	2021050590	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.24.1	8 Hours
Lymphadenopathy	v.24.1	
Malaise	v.24.1	
Pyrexia	v.24.1	0 Months

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03779356	5	2021-02-03	2021-08-17	MAH	2021-BI-075443	Study	Consumer/other non health professional

Serious report?
Serious

Death:	No	**Disability:**	No	**Congenital Anomaly:**	No
Life Threatening:	No	**Hospitalization:**	No	**Other Medically Important Conditions:**	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
64 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				Product used for unknown indication
NINTEDANIB ESILATE	Suspect	Capsules	Oral		1 every 12 Hours		Idiopathic pulmonary fibrosis
NINTEDANIB ESILATE	Suspect	Capsules	Oral	150.0 Milligram	1 every 12 Hours		Idiopathic pulmonary fibrosis
NINTEDANIB ESILATE	Suspect		Oral	100.0 Milligram	1 every 12 Hours		Idiopathic pulmonary fibrosis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal distension	v.24.1	
Abdominal pain upper	v.24.1	
Abdominal pain upper	v.24.1	
Alanine aminotransferase increased	v.24.1	
Asthenia	v.24.1	
Blood pressure increased	v.24.1	
Dizziness	v.24.1	
Flatulence	v.24.1	
Hepatic steatosis	v.24.1	
Liver function test abnormal	v.24.1	
Malaise	v.24.1	
Nausea	v.24.1	
Pain	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03784888	1	2021-02-04	2021-04-16	MAH	2021063551	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
79 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CITALOPRAM	Concomitant						
DILTIAZEM	Concomitant						
GALANTAMINE	Concomitant	NOT SPECIFIED					
HYDROCHLOROTHIAZIDE	Concomitant	Tablets					
LEVOTHYROXINE	Concomitant	NOT SPECIFIED					
MELATONIN	Concomitant	NOT SPECIFIED					
NITROFURANTOIN	Concomitant	NOT SPECIFIED					
PANTOPRAZOLE	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bradycardia	v.24.1	
Generalised tonic-clonic seizure	v.24.1	
Ventricular tachycardia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03785628	0	2021-02-04	2021-02-04	MAH	2021070220	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
93 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dyspnoea	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03791776	2	2021-02-08	2021-05-03	MAH	2021051558	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
34 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AZATHIOPRINE SODIUM	Concomitant		Oral	100.0 Milligram	1 every 1 Days		Systemic lupus erythematosus
COLCITINE	Concomitant		Oral	0.6 Milligram	2 every 1 Days		Pericarditis
HYDROXYCHLOROQUINE SULFATE	Concomitant						Systemic lupus erythematosus
PANTOLOC [PANTOPRAZOLE]	Concomitant			40.0 Milligram	1 every 1 Days		Gastric ulcer
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
SYNTHROID	Concomitant	NOT SPECIFIED	Oral	75.0 Milligram	1 every 1 Days		Hypothyroidism

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	1 Months
Fatigue	v.24.1	1 Months
Myalgia	v.24.1	1 Months
Systemic lupus erythematosus	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03792739	0	2021-02-08	2021-02-08	MAH	2021069837	Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
52 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cough	v.24.1	
Dyspnoea	v.24.1	
Hypertension	v.24.1	
Oesophageal disorder	v.24.1	
Paraesthesia	v.24.1	
Wheezing	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03796550	1	2021-02-10	2021-02-17	MAH	2021081504	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
46 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BACLOFEN	Concomitant	NOT SPECIFIED	Oral	10.0 Milligram	3 every 1 Days		
CLONAZEPAM	Concomitant	Tablets		2.0 Milligram	3 every 1 Days		Pain
DICLOFENAC	Concomitant		Oral	50.0 Milligram	2 every 1 Days		
DILANTIN [PHENYTOIN SODIUM]	Concomitant		Oral	120.0 Milligram	3 every 1 Days		Pain
HYDROMORPHONE HYDROCHLORIDE	Concomitant		Oral	6.0 Milligram	2 every 1 Days		
PANTOPRAZOLE	Concomitant	NOT SPECIFIED		40.0 Milligram	2 every 1 Days		
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anxiety	v.24.1	
Blood glucose decreased	v.24.1	
Fatigue	v.24.1	
Hypertension	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Paraesthesia	v.24.1	
Product supply issue	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03796658	1	2021-02-10	2021-02-19	MAH	2021071387	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
33 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bell's palsy	v.24.1	10 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03796755	0	2021-02-10	2021-02-10	MAH	2021075689	Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
33 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Feeling hot	v.24.1	
Pain	v.24.1	
Rash erythematous	v.24.1	
Rash papular	v.24.1	
Rash pruritic	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03796773	1	2021-02-10	2021-02-12	MAH	2021072686	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
38 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.24.1	
Dyspnoea	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Tachycardia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03798255	1	2021-02-10	2021-02-12	MAH	2021085718	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	E2B_03798259
Linked	E2B_03798259
Linked	E2B_03798259

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03798256	1	2021-02-10	2021-02-12	MAH	2021085723	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_03798259
Linked	E2B_03798259
Linked	
Linked	E2B_03798259

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypersensitivity	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03798259	1	2021-02-10	2021-02-12	MAH	2021013155	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_03798518
Linked	E2B_03798256
Linked	E2B_03798255
Linked	E2B_03798334
Linked	E2B_03798343
Linked	E2B_03798270
Linked	E2B_03798301
Linked	E2B_03798289
Linked	E2B_03798343
Linked	E2B_03798301
Linked	E2B_03798270
Linked	E2B_03798256
Linked	E2B_03798334
Linked	E2B_03798518
Linked	E2B_03798286
Linked	E2B_03798289

Record Type	Link AER** Number
Linked	E2B_03798343
Linked	E2B_03798289
Linked	E2B_03798518
Linked	E2B_03798255
Linked	E2B_03798301
Linked	
Linked	E2B_03798256
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	E2B_03798255
Linked	
Linked	E2B_03798270
Linked	E2B_03798286

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypersensitivity	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information

***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03798270	1	2021-02-10	2021-02-11	MAH	2021085715	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_03798259
Linked	E2B_03798259
Linked	E2B_03798259

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03798286	0	2021-02-10	2021-02-10	MAH	2021085720	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_03798259
Linked	E2B_03798259

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypersensitivity	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03798289	1	2021-02-10	2021-02-11	MAH	2021085716	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_03798259
Linked	E2B_03798259
Linked	E2B_03798259

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypersensitivity	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information

***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03798301	1	2021-02-10	2021-02-12	MAH	2021013393	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_03798259
Linked	E2B_03798259
Linked	E2B_03798259

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypersensitivity	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03798334	0	2021-02-10	2021-02-10	MAH	2021085722	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_03798259
Linked	E2B_03798259

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypersensitivity	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03798343	1	2021-02-10	2021-02-12	MAH	2021085719	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_03798259
Linked	E2B_03798259
Linked	E2B_03798259

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Unknown				COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03798518	1	2021-02-10	2021-02-12	MAH	2021085721	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_03798259
Linked	E2B_03798259
Linked	E2B_03798259

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypersensitivity	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03798605	1	2021-02-10	2021-02-18	MAH	2021092579	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
29 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cardiac flutter	v.24.1	
Palpitations	v.24.1	
Vaccination site erythema	v.24.1	0 Months
Vaccination site inflammation	v.24.1	0 Months
Vaccination site pain	v.24.1	0 Months
Vaccination site swelling	v.24.1	0 Months

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03803084	0	2021-02-11	2021-02-11	MAH	2021007865	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
46 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CETIRIZINE	Concomitant			10.0 Milligram	every 1 Days		Asthma
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
SALBUTAMOL	Concomitant	NOT SPECIFIED			As required	6.0 Years	Hypersensitivity

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.24.1	1 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03803596	1	2021-02-11	2021-03-25	MAH	2021090509	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
32 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_03803604
Linked	E2B_03803604
Linked	E2B_03803604
Linked	
Linked	E2B_03803604

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Paraesthesia oral	v.24.1	
Swelling face	v.24.1	
Type I hypersensitivity	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Urticaria	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03803604	2	2021-02-11	2021-03-25	MAH	2021090510	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
59 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_03803596
Linked	E2B_03803596
Linked	E2B_03803596
Linked	E2B_03803596

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dyspnoea	v.24.1	
Paraesthesia oral	v.24.1	
Swelling face	v.24.1	
Type I hypersensitivity	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03804040	12	2021-02-11	2021-12-15	MAH	MYERS SQUIBB COMPANY	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
73 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CARVEDILOL	Concomitant	Tablets	Unknown				Product used for unknown indication
CLOPIDOGREL	Concomitant	Tablets	Unknown				Product used for unknown indication
COVID-19 VACCINE	Suspect		Unknown				Prophylaxis
FUROSEMIDE	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication
HYDROMORPH CONTIN	Concomitant	CAPSULE, SUSTAINED-RELEASE	Unknown				Product used for unknown indication

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
IPILIMUMAB	Suspect		Intravenous (not otherwise specified)	1.0 mg/kg	1 every 6 Weeks		Non-small cell lung cancer
NIVOLUMAB	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	360.0 Milligram	1 every 3 Weeks		Non-small cell lung cancer
PANTOPRAZOLE SODIUM	Concomitant		Unknown				Product used for unknown indication
RATIO-ZOPICLONE	Concomitant	Tablets	Unknown				Product used for unknown indication
SYNTHROID	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Alopecia	v.24.1	
Arthralgia	v.24.1	
Breast pain	v.24.1	
Burning sensation	v.24.1	
Chills	v.24.1	
Constipation	v.24.1	
Diarrhoea	v.24.1	
Diverticulitis	v.24.1	
Dry skin	v.24.1	
Dyspepsia	v.24.1	
Energy increased	v.24.1	
Erythema	v.24.1	
Eye pain	v.24.1	
Fatigue	v.24.1	
Feeling cold	v.24.1	
Flushing	v.24.1	
Galactorrhoea	v.24.1	
Headache	v.24.1	
Hyperhidrosis	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypoaesthesia	v.24.1	
Increased appetite	v.24.1	
Infusion related reaction	v.24.1	
Myalgia	v.24.1	
Nasopharyngitis	v.24.1	
Night sweats	v.24.1	
Off label use	v.24.1	
Pain in extremity	v.24.1	
Peripheral coldness	v.24.1	
Peripheral swelling	v.24.1	
Photosensitivity reaction	v.24.1	
Pruritus	v.24.1	
Pyrexia	v.24.1	
Rash pruritic	v.24.1	
Somnolence	v.24.1	
Tinnitus	v.24.1	
Urinary tract infection	v.24.1	
Vomiting	v.24.1	
Weight increased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03804107	2	2021-02-11	2021-02-25	MAH	2021098823	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
67 Years	Female	157 Centimeter	95 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
HYDROXYCHLOROQUINE SULFATE	Concomitant						Sjogren's syndrome
INFLUENZA VACCINES	Concomitant	NOT SPECIFIED					Immunisation
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
PROPRANOLOL	Concomitant	NOT SPECIFIED					Hypertension
VERAPAMIL	Concomitant						Hypertension

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.24.1	1 Days
Chest discomfort	v.24.1	1 Days

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypoaesthesia oral	v.24.1	1 Days
Paraesthesia oral	v.24.1	1 Days
Paraesthesia oral	v.24.1	1 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03806832	2	2021-02-12	2021-03-02	MAH	2021092919	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
48 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ETHINYL ESTRADIOL/NORGESTIMATE	Concomitant		Oral				Oral contraception
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pulmonary embolism	v.24.1	
Pulmonary infarction	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03807252	0	2021-02-12	2021-02-12	MAH	2021069788	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
44 Years				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Herpes zoster	v.24.1	
Inappropriate schedule of product administration	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03807347	1	2021-02-12	2021-04-13	MAH	2021136736	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_03807353
Linked	
Linked	
Linked	E2B_03807357
Linked	E2B_03807353
Linked	E2B_03807353

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Transplacental		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Exposure during pregnancy	v.24.1	
Foetal growth restriction	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03807353	1	2021-02-12	2021-04-13	MAH	2021136735	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_03807347
Linked	
Linked	E2B_03807347
Linked	E2B_03807357
Linked	E2B_03807347

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Transplacental		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Exposure during pregnancy	v.24.1	
Foetal growth restriction	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03807357	1	2021-02-12	2021-04-13	MAH	2021136705	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
34 Years	Female	163 Centimeter	72 Kilogram	Recovered/resolved with sequelae

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_03807347
Linked	E2B_03807353

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abortion spontaneous	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03807661	0	2021-02-12	2021-02-12	MAH	2021099537	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic shock	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03807741	1	2021-02-12	2021-05-10	MAH	2020513999	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
60 Years	Female	168 Centimeter	72 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
PROPRANOLOL	Concomitant	NOT SPECIFIED		10.0 Milligram	3 every 1 Days		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.24.1	
Diarrhoea	v.24.1	2 Days
Dysgeusia	v.24.1	315 Minutes
Dysphagia	v.24.1	315 Minutes
Hypertension	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Paraesthesia oral	v.24.1	315 Minutes
Tongue pruritus	v.24.1	315 Minutes

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03811096	1	2021-02-15	2021-03-23	MAH	2021104876	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
91 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.24.1	
Drug ineffective	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03814629	6	2021-02-16	2021-11-25	MAH	MYERS SQUIBB COMPANY	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
65 Years	Female		56 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_04820859
Linked	E2B_04820859
Linked	E2B_04820859
Linked	E2B_04820859
Linked	E2B_04820859
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETAMINOPHEN	Concomitant		Unknown				Product used for unknown indication
ADVAIR	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication
COVID-19 VACCINE	Suspect		Unknown				Immunisation

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
DESOXIMETASONE	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication
INH	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication
ORENCIA	Suspect	Solution for infusion	Intravenous (not otherwise specified)	750.0 Milligram	1 every 4 Weeks		Rheumatoid arthritis, Product used for unknown indication
ORENCIA	Suspect		Intravenous (not otherwise specified)	750.0 Milligram	1 every 4 Weeks		Rheumatoid arthritis, Product used for unknown indication
VENLAFAXINE HYDROCHLORIDE	Concomitant		Unknown				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood pressure increased	v.24.1	
Breast abscess	v.24.1	24 Days
Fatigue	v.24.1	
Hypersomnia	v.24.1	
Injection site pain	v.24.1	
Nodule	v.24.1	
Pain	v.24.1	
Skin disorder	v.24.1	24 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03815830	1	2021-02-16	2021-03-01	MAH	2021112309	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
53 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
EZETIMIBE	Concomitant	Tablets					Blood cholesterol increased
IBUPROFEN	Concomitant	NOT SPECIFIED					Arthritis
LEFLUNOMIDE	Concomitant	NOT SPECIFIED	Oral				Arthritis
PANTOPRAZOLE	Concomitant	NOT SPECIFIED	Oral				Gastric disorder
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
SERTRALINE	Concomitant	Capsules	Oral				Depression
SULFASALAZINE	Concomitant	NOT SPECIFIED	Oral				Arthritis
TRAZODONE	Concomitant						Sleep disorder

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Diplopia	v.24.1	
Headache	v.24.1	7 Days
IVth nerve paralysis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03816935	2	2021-02-17	2021-04-19	MAH	2021111748	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
52 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
JANUMET	Concomitant	Tablets					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Neck pain	v.24.1	
Pain in extremity	v.24.1	
Vaccination site pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03817434	1	2021-02-17	2021-02-26	MAH	2021112412	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
42 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AVAMYS	Concomitant	SPRAY, METERED DOSE					
DEXILANT	Concomitant	CAPSULE, DELAYED RELEASE					
OLODATEROL HYDROCHLORIDE/TIOTROPIUM BROMIDE MONOHYDRATE	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
PREDNISONE	Concomitant	NOT SPECIFIED					
VENTOLIN	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cough	v.24.1	
Hypersensitivity	v.24.1	1 Days
Pulmonary embolism	v.24.1	
Wheezing	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03821600	2	2021-02-18	2021-03-09	MAH	2021123373	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
23 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Ageusia	v.24.1	
Bell's palsy	v.24.1	
Eyelid function disorder	v.24.1	
Facial pain	v.24.1	
Hypoacusis	v.24.1	
Malaise	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pain	v.24.1	
Pain in jaw	v.24.1	
Psychotic disorder due to a general medical condition	v.24.1	
Speech disorder	v.24.1	
Temporomandibular joint syndrome	v.24.1	
Visual impairment	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information

***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03821610	1	2021-02-18	2021-04-09	MAH	2021106312	Spontaneous	Other health professional

Serious report?	Death:	Disability:	Congenital Anomaly:
Serious	No	No	No
	Life Threatening:	**Hospitalization:**	**Other Medically Important Conditions:**
	No	No	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
62 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
LYRICA	Concomitant	Capsules	Oral				Neuralgia
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
PROPRANOLOL HYDROCHLORIDE	Concomitant		Oral				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain	v.24.1	4 Days
Arrhythmia	v.24.1	153 Hours
Chills	v.24.1	2 Days
Disturbance in attention	v.24.1	6 Days

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	1 Days
Headache	v.24.1	
Myalgia	v.24.1	6 Days
Nausea	v.24.1	4 Days
Tinnitus	v.24.1	3 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03824745	0	2021-02-19	2021-02-19	MAH	2021040131	Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
50 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.24.1	-20
Dysphagia	v.24.1	0 Months
Dyspnoea	v.24.1	-17
Throat tightness	v.24.1	-17
Urticaria	v.24.1	30 Minutes

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03824936	0	2021-02-19	2021-02-19	MAH	2021138538	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.24.1	
Drug ineffective	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03825422	1	2021-02-19	2021-03-23	MAH	2021130029	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
33 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bell's palsy	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03826403	4	2021-02-22	2021-08-13	MAH	2020TUS033623	Study	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
60 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
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Record Type	Link AER** Number
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Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETYLSALICYLIC ACID	Concomitant	NOT SPECIFIED	Unknown	81.0 Milligram	1 every 1 Days		
ACYCLOVIR	Concomitant	Tablet	Unknown	400.0 Milligram	2 every 1 Days		
COVID-19 VACCINE	Suspect		Unknown				Product used for unknown indication
COVID-19 VACCINE	Suspect		Unknown				Product used for unknown indication
IXAZOMIB	Suspect		Oral	2.3 Milligram			Plasma cell myeloma
MACROGOL 400/PROPYLENE GLYCOL	Concomitant	Eye drops	Ophthalmic				Dry eye
ONDANSETRON	Concomitant		Oral	8.0 Milligram			
PREGABALIN	Suspect	Capsules	Unknown	50.0 Milligram	1 every 1 Days		Plasma cell myeloma
REVLIMID	Suspect	Capsules	Unknown	10.0 Milligram	1 every 1 Days	890.0 Days	Plasma cell myeloma
ZOLEDRONIC ACID MONOHYDRATE	Concomitant		Unknown		1 every 3 Months		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Constipation	v.24.1	
Diarrhoea	v.24.1	
Musculoskeletal stiffness	v.24.1	
Neuropathy peripheral	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pain	v.24.1	
Paraesthesia	v.24.1	
Pruritus	v.24.1	
Pyrexia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03827733	5	2021-02-22	2021-11-26	MAH	MYERS SQUIBB COMPANY	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
43 Years	Female		60 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				Prophylaxis
ORENCIA	Suspect		Intravenous (not otherwise specified)	750.0 Milligram	1 every 4 Weeks		Rheumatoid arthritis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Blood pressure increased	v.24.1	
Fall	v.24.1	
Upper limb fracture	v.24.1	
Urticaria	v.24.1	3 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03829481	0	2021-02-22	2021-02-22	MAH	2021130933	Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
86 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AMLODIPINE	Concomitant	Tablets		5.0 Milligram	every 1 Days		Hypertension
ATENOLOL/CHLORTHALIDONE	Concomitant		Oral		every 1 Days		Hypertension
EPOETIN ALFA	Concomitant		Subcutaneous		1 every 1 Weeks		Renal failure
FUROSEMIDE	Concomitant	NOT SPECIFIED		80.0 Milligram	every 1 Days		Renal failure
LORAZEPAM	Concomitant	NOT SPECIFIED	Oral	1.0 Milligram			Insomnia
MAGNESIUM	Concomitant	NOT SPECIFIED		500.0 Milligram	every 1 Days		Supplementation therapy
NORTRIPTYLINE HYDROCHLORIDE	Concomitant			25.0 Milligram	every 1 Days		Depression
PANTOPRAZOLE	Concomitant	NOT SPECIFIED	Oral	40.0 Milligram			Abdominal discomfort

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
ROSUVASTATIN	Concomitant	NOT SPECIFIED	Oral	10.0 Milligram			Hypercholesterolaemia

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Acute kidney injury	v.24.1	
Asthenia	v.24.1	
Decreased appetite	v.24.1	
Rash maculo-papular	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03830424	6	2021-02-23	2021-07-15	MAH	CA2021AMR049766	Study	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
73 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
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Linked	E2B_05076210
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Record Type	Link AER** Number
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Record Type	Link AER** Number
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Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AMITRIPTYLINE	Concomitant		Unknown				Product used for unknown indication
ATORVASTATIN	Concomitant	Tablets	Unknown				Product used for unknown indication
BUDESONIDE/FORMOTEROL FUMARATE	Concomitant		Unknown				Product used for unknown indication
COVID-19 VACCINE	Suspect		Unknown				COVID-19 prophylaxis
COVID-19 VACCINE	Suspect		Unknown				COVID-19 prophylaxis
DIAMICRON	Concomitant	Tablets	Unknown				Product used for unknown indication
LETROZOLE	Concomitant	Tablets	Unknown				Product used for unknown indication
MEPOLIZUMAB	Suspect	Powder for injection	Subcutaneous	100.0 Milligram			Product used for unknown indication, Asthma
MEPOLIZUMAB	Suspect		Subcutaneous	100.0 Milligram			Product used for unknown indication, Asthma
MEPOLIZUMAB	Suspect	Powder for injection	Subcutaneous	100.0 Milligram			Product used for unknown indication, Asthma

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
NASONEX	Concomitant	SPRAY, METERED DOSE	Unknown				Product used for unknown indication
PREDNISONE	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication
PROLIA PRE-FILLED SYRINGE. PRESERVATIVE-FREE.	Concomitant	SOLUTION SUBCUTANEOUS	Unknown				Bone disorder
SALBUTAMOL	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cataract operation	v.24.1	
Chemotherapy	v.24.1	
Contusion	v.24.1	
Fall	v.24.1	
Macular hole	v.24.1	
Retinal detachment	v.24.1	
Toe operation	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03831956	0	2021-02-23	2021-02-23	MAH	2021143485	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
50 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Erythema multiforme	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03831965	1	2021-02-23	2021-04-27	MAH	2021137722	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
32 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Fatigue	v.24.1	
Hypersomnia	v.24.1	
Hypoaesthesia	v.24.1	
Neuralgia	v.24.1	
Pain in extremity	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Paraesthesia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03832867	0	2021-02-23	2021-02-23	MAH	2021154117	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.24.1	
Drug ineffective	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information

***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03833163	2	2021-02-23	2021-10-29	MAH	MYERS SQUIBB COMPANY	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
84 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				Immunisation
ORENCIA	Suspect		Subcutaneous	125.0 Milligram	1 every 1 Weeks		Rheumatoid arthritis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Atrial fibrillation	v.24.1	
Back pain	v.24.1	
Musculoskeletal stiffness	v.24.1	2 Months
Pain in extremity	v.24.1	
Rheumatoid arthritis	v.24.1	
Vitamin B12 decreased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03834453	3	2021-02-24	2021-07-01	MAH	2021-04513	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
50 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
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Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AMLODIPINE BESILATE/TELMISARTAN	Concomitant						
CORTEF	Concomitant	NOT SPECIFIED		10.0 Milligram			
CORTEF	Concomitant			2.5 Milligram	every 16 Hours		
CORTEF	Concomitant			5.0 Milligram	every 12 Hours		

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Unknown			1.0 Days	COVID-19 prophylaxis
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect					1.0 Days	COVID-19 prophylaxis
CYCLOBENZAPRINE	Concomitant						
DESMOPRESSIN	Concomitant						
OXAZEPAM	Concomitant	Tablets					
PANTOPRAZOLE	Concomitant	NOT SPECIFIED					
SOMATULINE AUTOGEL PRE-FILLED SYRINGE	Suspect	SOLUTION (EXTENDED RELEASE)	Subcutaneous	120.0 Milligram	every 6 Weeks		Acromegaly
SOMATULINE AUTOGEL PRE-FILLED SYRINGE	Suspect	Solution for injection	Subcutaneous	120.0 Milligram	every 4 Weeks		Acromegaly
SYNTHROID	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.24.1	0 Months
Discomfort	v.24.1	15 Minutes
Discomfort	v.24.1	
Disease progression	v.24.1	
Drug ineffective	v.24.1	
Dysstasia	v.24.1	
Fatigue	v.24.1	1 Days
Fatigue	v.24.1	
Fatigue	v.24.1	0 Months
Headache	v.24.1	0 Months
Hot flush	v.24.1	-31
Injection site pain	v.24.1	1 Days
Malaise	v.24.1	
Nasopharyngitis	v.24.1	
Pyrexia	v.24.1	0 Months

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03834774	0	2021-02-24	2021-02-24	MAH	2021123409	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
28 Years	Female	165 Centimeter	49 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Beta haemolytic streptococcal infection	v.24.1	
Cough	v.24.1	
Dysphagia	v.24.1	
Lymphadenopathy	v.24.1	
Oropharyngeal pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03836451	0	2021-02-24	2021-02-24	MAH	2021154887	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
50 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Lymphadenopathy	v.24.1	1 Months

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03841918	0	2021-02-26	2021-02-26	MAH	20210111196	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				Product used for unknown indication
STELARA	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Influenza like illness	v.24.1	
Malaise	v.24.1	
Myalgia	v.24.1	
Nephrolithiasis	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Sinus congestion	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03845229	0	2021-03-01	2021-03-01	MAH	2021026035	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
35 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BIOFLEX [GLUCOSAMINE SULFATE]	Concomitant						
BIOTIN/CALCIUM D-PANTOTHENATE/D-ALPHA TOCOPHERYL ACETATE/FOLIC ACID/NICOTINAMIDE/PYRIDOXINE HYDROCHLORIDE/RIBOFLAVIN/THIAMINE HYDROCHLORIDE/VITAMIN A/VITAMIN B12/VITAMIN C/VITAMIN D3	Concomitant						
COLLAGEN	Concomitant						

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Arthralgia	v.24.1	37 Hours
Condition aggravated	v.24.1	
Hypoaesthesia	v.24.1	
Myalgia	v.24.1	
Pain	v.24.1	
Pain in extremity	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03846259	1	2021-03-01	2021-04-14	MAH	2021169780	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Ear pruritus	v.24.1	
Eyelid oedema	v.24.1	
Eyelids pruritus	v.24.1	
Hypersensitivity	v.24.1	
Lip pruritus	v.24.1	
Oedema	v.24.1	
Pruritus	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Tongue pruritus	v.24.1	
Urticaria	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information

***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03846273	1	2021-03-01	2021-03-07	MAH	2021170765	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
30 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Months	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.24.1	
Drug ineffective	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03849637	0	2021-03-02	2021-03-02	MAH	2021171411	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
41 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AVAMYS	Concomitant	SPRAY, METERED DOSE		1.0 Dosage forms	2 every 1 Days		Atopic keratoconjunctivitis
BISOPROLOL	Concomitant			1.25 Milligram	every 1 Days		Sinus tachycardia
GABAPENTIN	Concomitant	NOT SPECIFIED		200.0 Milligram	every 1 Days		Complex regional pain syndrome
PANTOPRAZOLE MAGNESIUM	Concomitant			40.0 Milligram	every 1 Days		Reflux gastritis
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
RESTASIS	Concomitant	EMULSION					Atopic keratoconjunctivitis
SINGULAIR	Concomitant	NOT SPECIFIED		10.0 Milligram			Atopic keratoconjunctivitis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.24.1	
Chest discomfort	v.24.1	
Feeling hot	v.24.1	
Hypoaesthesia oral	v.24.1	
Laryngospasm	v.24.1	
Throat tightness	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03850392	3	2021-03-02	2021-03-23	MAH	2021193323	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
24 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
METHOTREXATE	Concomitant	NOT SPECIFIED			1 every 1 Weeks		Arthritis
NAPROXEN	Concomitant	NOT SPECIFIED					
PANTOLOC [PANTOPRAZOLE]	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
STELARA	Concomitant	SOLUTION SUBCUTANEOUS			1 every 3 Months		Seronegative arthritis
VITAMIN D	Concomitant						
ZOFRAN [ONDANSETRON]	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.24.1	6 Hours

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03850601	3	2021-03-03	2021-11-15	MAH	21K-028-3790762-00	Study	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
58 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular			1.0 Months	COVID-19 prophylaxis
COVID-19 VACCINE	Suspect		Intramuscular			0.0	COVID-19 prophylaxis
COVID-19 VACCINE	Suspect		Intramuscular			0.0	COVID-19 prophylaxis

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
DESOXIMETASONE	Suspect		Unknown				Product used for unknown indication
DESOXIMETASONE	Suspect	NOT SPECIFIED	Unknown				Product used for unknown indication
PREDNISONE	Concomitant	NOT SPECIFIED					Product used for unknown indication
RINVOQ	Suspect	TABLET (EXTENDED-RELEASE)	Oral	15.0 Milligram	1 every 1 Days	2.0 Years	Rheumatoid arthritis
RINVOQ	Suspect	Prolonged-release tablet	Oral	15.0 Milligram	1 every 1 Days		Rheumatoid arthritis
RINVOQ	Suspect	Prolonged-release tablet	Oral	15.0 Milligram	1 every 1 Days	115.0	Rheumatoid arthritis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaemia	v.24.1	
Back pain	v.24.1	2 Days
Blood iron decreased	v.24.1	
Dizziness	v.24.1	2 Days
Dizziness	v.24.1	
Dyspnoea	v.24.1	
Malaise	v.24.1	2 Days
Middle insomnia	v.24.1	
Mobility decreased	v.24.1	
Nephrolithiasis	v.24.1	2 Days
Pollakiuria	v.24.1	
Rheumatoid arthritis	v.24.1	
Syncope	v.24.1	
Tinnitus	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03863074	1	2021-03-05	2021-03-15	MAH	2021223905	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
63 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_03894550
Linked	
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.24.1	1 Hours

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03869130	0	2021-03-08	2021-03-08	MAH	2021208937	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	E2B_03874394
Linked	E2B_03874394

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown			1.0 Months	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.24.1	
Drug ineffective	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Off label use	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03869137	0	2021-03-08	2021-03-08	MAH	2021208932	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_03874394
Linked	E2B_03874394
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Months	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.24.1	
Drug ineffective	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Off label use	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03869138	0	2021-03-08	2021-03-08	MAH	2021208941	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_03874394
Linked	E2B_03874394
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Months	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.24.1	
Drug ineffective	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Off label use	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03869141	0	2021-03-08	2021-03-08	MAH	2021208940	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	E2B_03874394
Linked	E2B_03874394

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Months	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.24.1	
Drug ineffective	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Off label use	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03869152	0	2021-03-08	2021-03-08	MAH	2021208942	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	E2B_03874394
Linked	E2B_03874394

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Months	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.24.1	
Drug ineffective	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Off label use	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03869156	0	2021-03-08	2021-03-08	MAH	2021208938	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_03874394
Linked	
Linked	E2B_03874394

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Months	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.24.1	
Drug ineffective	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Off label use	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03869167	0	2021-03-08	2021-03-08	MAH	2021208936	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	E2B_03874394
Linked	E2B_03874394

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Months	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.24.1	
Drug ineffective	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Off label use	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03869168	0	2021-03-08	2021-03-08	MAH	2021208934	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_03874394
Linked	E2B_03874394
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Months	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.24.1	
Drug ineffective	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Off label use	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03869178	0	2021-03-08	2021-03-08	MAH	2021208939	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	E2B_03874394
Linked	E2B_03874394

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Months	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.24.1	
Drug ineffective	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Off label use	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03869194	0	2021-03-08	2021-03-08	MAH	2021208935	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	E2B_03874394
Linked	E2B_03874394

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Months	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.24.1	
Drug ineffective	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Off label use	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03869352	0	2021-03-08	2021-03-08	MAH	2021201032	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
41 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
TRAZODONE	Concomitant						Sleep disorder

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Back pain	v.24.1	
Neuralgia	v.24.1	
Paraesthesia	v.24.1	
Pruritus	v.24.1	
Reflexes abnormal	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03869786	0	2021-03-08	2021-03-08	MAH	2021239714	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
45 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
NALTREXONE	Concomitant		Oral				
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic shock	v.24.1	
Dizziness	v.24.1	
Headache	v.24.1	
Heart rate decreased	v.24.1	
Heart rate increased	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hyperhidrosis	v.24.1	
Hypoaesthesia	v.24.1	
Muscle spasms	v.24.1	
Nausea	v.24.1	
Oxygen saturation decreased	v.24.1	
Pain in extremity	v.24.1	
Paraesthesia	v.24.1	
Pulse volume decreased	v.24.1	
Rhinorrhoea	v.24.1	
Syncope	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03869803	1	2021-03-08	2021-03-16	MAH	2021238453	Spontaneous	Physician

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
31 Years	Female	170 Centimeter	62 Kilogram	Recovered/resolved with sequelae

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETAMINOPHEN	Concomitant	NOT SPECIFIED			As required		
IBUPROFEN	Concomitant	NOT SPECIFIED	Oral				Headache
MINERALS NOS/VITAMINS NOS	Concomitant		Oral		1 every 1 Days		
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Ectopic pregnancy	v.24.1	1 Days
Off label use	v.24.1	
Product use issue	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03874394	1	2021-03-09	2021-05-06	MAH	2021205729	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_03874459
Linked	E2B_03874483
Linked	E2B_03874485
Linked	E2B_03885108
Linked	E2B_03874410
Linked	E2B_03874424
Linked	E2B_03874396
Linked	E2B_03874406
Linked	E2B_03874483
Linked	E2B_03869167
Linked	E2B_03869168
Linked	E2B_03869130
Linked	E2B_03874397
Linked	E2B_03874413
Linked	
Linked	
Linked	E2B_03869194

Record Type	Link AER** Number
Linked	
Linked	
Linked	E2B_03869156
Linked	
Linked	
Linked	
Linked	E2B_03869141
Linked	E2B_03869138
Linked	E2B_03869152
Linked	E2B_03869137
Linked	E2B_03869178
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	E2B_03869167
Linked	E2B_03869168
Linked	E2B_03869130
Linked	
Linked	
Linked	E2B_03874397
Linked	E2B_03874399
Linked	E2B_03874402
Linked	E2B_03874404
Linked	E2B_03885108
Linked	E2B_03869156
Linked	E2B_03874485
Linked	E2B_03874418
Linked	E2B_03874399
Linked	E2B_03869141
Linked	E2B_03869138
Linked	E2B_03869152
Linked	E2B_03869137

Record Type	Link AER** Number
Linked	E2B_03869178
Linked	E2B_03874459
Linked	E2B_03874456
Linked	E2B_03874402
Linked	E2B_03869194
Linked	E2B_03874404
Linked	E2B_03874406
Linked	E2B_03874410
Linked	E2B_03874413
Linked	E2B_03874418
Linked	E2B_03874424
Linked	E2B_03874456

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Months	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.24.1	
Drug ineffective	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Off label use	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03874396	0	2021-03-09	2021-03-09	MAH	2021208919	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	E2B_03874394

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Months	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.24.1	
Drug ineffective	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Off label use	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03874397	0	2021-03-09	2021-03-09	MAH	2021208920	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_03874394
Linked	E2B_03874394

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Months	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.24.1	
Drug ineffective	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Off label use	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03874399	0	2021-03-09	2021-03-09	MAH	2021208923	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_03874394
Linked	E2B_03874394

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Months	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.24.1	
Drug ineffective	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Off label use	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03874402	0	2021-03-09	2021-03-09	MAH	2021208933	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_03874394
Linked	E2B_03874394

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Months	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.24.1	
Drug ineffective	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Off label use	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03874404	0	2021-03-09	2021-03-09	MAH	2021208918	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_03874394
Linked	E2B_03874394

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Months	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.24.1	
Drug ineffective	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Off label use	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03874406	0	2021-03-09	2021-03-09	MAH	2021208922	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_03874394
Linked	E2B_03874394

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Months	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.24.1	
Drug ineffective	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Off label use	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03874410	0	2021-03-09	2021-03-09	MAH	2021208925	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_03874394
Linked	E2B_03874394

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Months	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.24.1	
Drug ineffective	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Off label use	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03874413	0	2021-03-09	2021-03-09	MAH	2021208926	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_03874394
Linked	E2B_03874394

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Months	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.24.1	
Drug ineffective	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Off label use	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03874418	0	2021-03-09	2021-03-09	MAH	2021208930	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_03874394
Linked	E2B_03874394

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Months	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.24.1	
Drug ineffective	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Off label use	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03874424	0	2021-03-09	2021-03-09	MAH	2021208924	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_03874394
Linked	E2B_03874394

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Months	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.24.1	
Drug ineffective	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Off label use	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03874456	0	2021-03-09	2021-03-09	MAH	2021208929	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_03874394
Linked	E2B_03874394

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Months	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.24.1	
Drug ineffective	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Off label use	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03874459	0	2021-03-09	2021-03-09	MAH	2021208927	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_03874394
Linked	E2B_03874394

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Months	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.24.1	
Drug ineffective	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Off label use	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03874483	0	2021-03-09	2021-03-09	MAH	2021208931	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_03874394
Linked	E2B_03874394

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Months	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.24.1	
Drug ineffective	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Off label use	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03874485	0	2021-03-09	2021-03-09	MAH	2021208921	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_03874394
Linked	E2B_03874394

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Months	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.24.1	
Drug ineffective	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Off label use	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03874583	0	2021-03-09	2021-03-09	MAH	2021193477	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bell's palsy	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03875301	0	2021-03-09	2021-03-09	MAH	2021215856	Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
34 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Erythema	v.24.1	
Swelling face	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03875435	0	2021-03-09	2021-03-09	MAH	2021215876	Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
34 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03878696	1	2021-03-10	2021-06-28	MAH	MOD-2021-028850	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
37 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	1.0 Dosage forms			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenopia	v.24.1	
Dizziness	v.24.1	
Extraocular muscle paresis	v.24.1	
Headache	v.24.1	
Hypoaesthesia	v.24.1	
Nausea	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Paraesthesia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information

***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03879331	0	2021-03-10	2021-03-10	MAH	2021216520	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
21 Years	Male	175 Centimeter	81 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Months	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Malaise	v.24.1	
Penis disorder	v.24.1	
Testicular retraction	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03879567	0	2021-03-10	2021-03-10	MAH	2021258664	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
52 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	
Malaise	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03882628	3	2021-03-11	2021-06-10	MAH	2021148153	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
36 Years	Female	180 Centimeter	97 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
FERROUS SULFATE/FOLIC ACID/NICOTINAMIDE/PYRIDOXINE HYDROCHLORIDE/RIBOFLAVIN/THIAMINE MONONITRATE/VITAMIN C	Concomitant			1.0 Dosage forms	every 1 Days		
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Gestational diabetes	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Lymphadenopathy	v.24.1	
Maternal exposure during pregnancy	v.24.1	
Vaccination site pain	v.24.1	1 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03883198	2	2021-03-11	2021-03-18	MAH	2021252679	Spontaneous	Physician

Serious report?	Death:	Yes	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
83 Years	Female			Fatal

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BISOPROLOL	Concomitant						
CLOPIDOGREL BISULFATE	Concomitant						
LASIX [FUROSEMIDE]	Concomitant						
NITROGLYCERIN	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Death	v.24.1	
Fall	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03883909	1	2021-03-11	2021-10-20	MAH	21K-028-3805546-00	Study	Consumer/other non health professional

Serious report?
Not Serious

Death:	No	Disability:	No	Congenital Anomaly:	No
Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
63 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	
Linked	E2B_04402055
Linked	
Linked	
Linked	E2B_04402055

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular			1.0 Days	COVID-19 immunisation
HUMIRA	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous	40.0 Milligram	1 every 2 Weeks	11.0 Years	Psoriatic arthropathy, Psoriasis
HUMIRA	Suspect	Solution for injection in pre-filled pen	Subcutaneous	40.0 Milligram	1 every 7 Days		Psoriatic arthropathy, Psoriasis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Depressed mood	v.24.1	
Insomnia	v.24.1	
Pain	v.24.1	
Psoriasis	v.24.1	
Rash	v.24.1	
Therapeutic product effect decreased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03885108	0	2021-03-11	2021-03-11	MAH	2021208928	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_03874394
Linked	E2B_03874394

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Months	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.24.1	
Drug ineffective	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Off label use	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03885110	0	2021-03-11	2021-03-11	MAH	2021185058	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
67 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ATORVASTATIN	Concomitant	Tablets					
CHLORTHALIDONE	Concomitant	Tablets					
LYRICA	Concomitant	Capsules					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
TEVA-DULOXETINE	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Diarrhoea	v.24.1	
Eye irritation	v.24.1	
Fatigue	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.24.1	
Lacrimation increased	v.24.1	
Lethargy	v.24.1	
Mucosal disorder	v.24.1	
Myalgia	v.24.1	
Pruritus	v.24.1	
Rhinorrhoea	v.24.1	
Sneezing	v.24.1	
Tenderness	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03889746	1	2021-03-12	2021-03-24	MAH	2021216129	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
43 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BUDESONIDE/FORMOTEROL FUMARATE	Concomitant				2 every 1 Days		
BUPROPION	Concomitant		Oral	150.0 Milligram	every 1 Days		
IBUPROFEN	Concomitant	NOT SPECIFIED					
MONTELUKAST	Concomitant	NOT SPECIFIED	Oral	10.0 Milligram	every 1 Days		
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
VENTOLIN [SALBUTAMOL SULFATE]	Concomitant				As required		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest discomfort	v.24.1	-56

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.24.1	20 Minutes
Loss of consciousness	v.24.1	-56
Paraesthesia oral	v.24.1	-56
Pulse volume decreased	v.24.1	-56
Swollen tongue	v.24.1	20 Minutes
Tachycardia	v.24.1	20 Minutes
Urticaria	v.24.1	20 Minutes
Vaccination site urticaria	v.24.1	20 Minutes

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03890239	0	2021-03-12	2021-03-12	MAH	2021224049	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
46 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CELEBREX	Concomitant	Capsules	Oral				Arthritis
CLONAZEPAM	Concomitant	Tablets	Oral				Anxiety
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	1 Days
Headache	v.24.1	
Hypertension	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03890286	0	2021-03-12	2021-03-12	MAH	2021228106	Spontaneous	Lawyer

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.24.1	
Facial paralysis	v.24.1	
Headache	v.24.1	
Lip swelling	v.24.1	
Paraesthesia	v.24.1	
Pruritus	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03890590	0	2021-03-12	2021-03-12	MAH	2021223930	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
59 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_03911215

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Rash	v.24.1	
Thrombocytopenia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03894550	0	2021-03-15	2021-03-15	MAH	2021223909	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
25 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_03863074

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03894565	0	2021-03-15	2021-03-15	MAH	2021223691	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
46 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.24.1	
Hypertension	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03898927	2	2021-03-16	2021-06-15	MAH	MOD-2021-031350	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
39 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BETA-CAROTENE/CALCIUM SULFATE/D-ALPHA TOCOPHERYL ACETATE/FERROUS FUMARATE/FOLIC ACID/NICOTINAMIDE/PYRIDOXINE HYDROCHLORIDE/RIBOFLAVIN/THIAMINE MONONITRATE/VITAMIN A ACETATE/VITAMIN B12/VITAMIN C/VITAMIN D3/ZINC OXIDE	Concomitant						Product used for unknown indication
CALCIUM CARBONATE/VITAMIN D3	Concomitant		Oral				Routine health maintenance

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CHROMIUM/COPPER/FOLIC ACID/INOSITOL/MAGNESIUM/MANGANESE/NICOTINAMIDE/PANTOTHENIC ACID/POTASSIUM/PYRIDOXINE HYDROCHLORIDE/RIBOFLAVIN/SELENIUM/VITAMIN A/VITAMIN B1/VITAMIN B12/VITAMIN C/VITAMIN E NOS/ZINC	Concomitant						Product used for unknown indication
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	1.0 Dosage forms			COVID-19 immunisation
UBIDECARENONE	Concomitant						Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Autoimmune thyroiditis	v.24.1	
Goitre	v.24.1	
Hyperthyroidism	v.24.1	
Muscle contractions involuntary	v.24.1	
Muscle twitching	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03905348	1	2021-03-17	2021-05-25	MAH	2021240446	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
34 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abortion spontaneous	v.24.1	1 Months
Off label use	v.24.1	
Product use issue	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03911136	0	2021-03-18	2021-03-18	MAH	2021252010	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Coeliac disease	v.24.1	
Diarrhoea	v.24.1	
Pain	v.24.1	
Weight decreased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03911215	1	2021-03-18	2021-03-18	MAH	2021223573	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
59 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_03890590

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Petechiae	v.24.1	
Purpura	v.24.1	
Rash	v.24.1	
Thrombocytopenia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03911315	1	2021-03-18	2021-03-24	MAH	2021263365	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
25 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
TYLENOL	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypoaesthesia	v.24.1	
Peripheral coldness	v.24.1	
Rash	v.24.1	105 Minutes
Swelling face	v.24.1	1050 Minutes
Urticaria	v.24.1	105 Minutes

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Vaccination site pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03913276	2	2021-03-19	2021-07-15	MAH	MOD-2021-029201	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
69 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASA	Concomitant	NOT SPECIFIED	Oral	81.0 Milligram	1 every 1 Days		Cardiac disorder
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	1.0 Dosage forms			COVID-19 immunisation
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	Injection	Intramuscular	1.0 Dosage forms			COVID-19 immunisation
LACTULOSE	Concomitant		Oral	17.2 Milligram			Constipation
LIPITOR	Concomitant	NOT SPECIFIED	Oral	20.0 Milligram	1 every 1 Days		Dyslipidaemia

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PROLIA PRE-FILLED SYRINGE. PRESERVATIVE-FREE.	Concomitant	SOLUTION SUBCUTANEOUS	Subcutaneous				Osteoporosis
VALPROIC ACID	Concomitant	NOT SPECIFIED	Oral	125.0 Milligram			Seizure

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dermatitis bullous	v.24.1	18 Days
Erythema	v.24.1	
Hypersensitivity	v.24.1	25470 Minutes
Pruritus	v.24.1	18 Days
Vaccination site rash	v.24.1	18 Days
Vaccination site vesicles	v.24.1	18 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03920045	2	2021-03-22	2021-05-07	MAH	2021275610	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
38 Years	Female			Recovered/resolved with sequelae

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	
Lymphadenopathy	v.24.1	
Swelling face	v.24.1	
Vision blurred	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03920083	1	2021-03-22	2021-03-26	MAH	2021262524	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
47 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
IRON	Concomitant						
NIFEDIPINE	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
VENLAFAXINE	Concomitant						
VITAMIN D [COLECALCIFEROL]	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Disease recurrence	v.24.1	
Pericarditis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03921776	2	2021-03-22	2021-05-06	MAH	2021253074	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
38 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	1 Days
Disease recurrence	v.24.1	1 Days
Lymphadenopathy	v.24.1	
Pain in extremity	v.24.1	
Pallor	v.24.1	1 Days
Syncope	v.24.1	1 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03922463	0	2021-03-22	2021-03-22	MAH	2021252021	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bell's palsy	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03922655	0	2021-03-22	2021-03-22	MAH	2021259225	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
68 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASA	Concomitant	NOT SPECIFIED	Oral	80.0 Milligram			
DEXILANT	Concomitant	CAPSULE, DELAYED RELEASE	Oral	60.0 Milligram			
FINASTERIDE	Concomitant	Tablets	Oral	5.0 Milligram	every 1 Days		
GABAPENTIN	Concomitant	NOT SPECIFIED	Oral	900.0 Milligram	1 every 1 Days		
METFORMIN	Concomitant		Oral	500.0 Milligram	every 1 Days		
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
ROSUVASTATIN CALCIUM	Concomitant		Oral	20.0 Milligram			
VALSARTAN	Concomitant	NOT SPECIFIED	Oral				
VITAMIN B COMPLEX	Concomitant		Oral				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bell's palsy	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03923161	0	2021-03-22	2021-03-22	MAH	2021251669	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
31 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MINERALS NOS/VITAMINS NOS	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.24.1	6 Days
Fatigue	v.24.1	6 Days
Headache	v.24.1	6 Days
Nausea	v.24.1	6 Days
Presyncope	v.24.1	6 Days

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Syncope	v.24.1	6 Days
Tremor	v.24.1	6 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03924602	1	2021-03-22	2021-05-21	MAH	2021251371	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
40 Years	Female			Recovered/resolved with sequelae

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
IRON + VITAMIN B12 CHEWABLE	Concomitant						Supplementation therapy
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	2 Hours
Hypoaesthesia oral	v.24.1	2 Hours
Paraesthesia oral	v.24.1	2 Hours
Pharyngeal hypoaesthesia	v.24.1	2 Hours
Pharyngeal paraesthesia	v.24.1	2 Hours

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03924661	2	2021-03-22	2021-06-01	MAH	2021250802	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
34 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BIOTIN	Concomitant	NOT SPECIFIED					
IBUPROFEN	Concomitant						
MELATONIN	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
TYLENOL	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anxiety	v.24.1	
Breast pain	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	
Hypoaesthesia	v.24.1	
Lymphadenopathy	v.24.1	
Pain in extremity	v.24.1	
Paraesthesia	v.24.1	
Peripheral swelling	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03926933	3	2021-03-23	2021-06-24	MAH	MOD-2021-039615	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
69 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	1.0 Dosage forms			COVID-19 immunisation
OMEGA 3 [FISH OIL]	Concomitant		Unknown	1000.0 Milligram	1 every 1 Days		Product used for unknown indication
PLANTAGO OVATA	Concomitant		Unknown	1.0 Dosage forms	1 every 1 Days		Product used for unknown indication
VITAMIN C [ASCORBIC ACID]	Concomitant		Unknown	500.0 Milligram	2 every 1 Days		Product used for unknown indication

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
VITAMIN D3	Concomitant		Unknown	1000.0 IU (International Unit)	2 every 1 Days		Product used for unknown indication
ZINC CHELATE	Concomitant		Unknown	50.0 Milligram	1 every 1 Days		Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Aura	v.24.1	
Diarrhoea	v.24.1	
Dysarthria	v.24.1	
Fatigue	v.24.1	
Migraine	v.24.1	
Musculoskeletal discomfort	v.24.1	
Night sweats	v.24.1	
Pain in extremity	v.24.1	
Paraesthesia	v.24.1	
Product dose omission issue	v.24.1	
Pyrexia	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03928849	0	2021-03-23	2021-03-23	MAH	2021269377	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
26 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bell's palsy	v.24.1	24 Hours
Influenza like illness	v.24.1	2 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03928911	12	2021-03-23	2021-12-14	MAH	2021-07384	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
71 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_03651501
Linked	
Linked	
Linked	
Linked	E2B_03651501
Linked	
Linked	
Linked	
Linked	
Linked	E2B_03651501
Linked	
Linked	
Linked	
Linked	E2B_03651501
Linked	
Linked	
Linked	

Record Type	Link AER** Number
Linked	E2B_03651501
Linked	
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Linked	E2B_03651501
Linked	
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Linked	
Linked	E2B_03651501
Linked	
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Linked	E2B_03651501
Linked	
Linked	
Linked	
Linked	E2B_03651501
Linked	
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ATENOLOL	Concomitant	Tablets					
COLCHICINE	Concomitant	Tablets					
COVID-19 VACCINE	Suspect		Unknown				COVID-19 prophylaxis
GABAPENTIN	Concomitant	NOT SPECIFIED					
GLICLAZIDE	Concomitant	Tablets					
HYDROMORPHONE	Concomitant	NOT SPECIFIED					
PANTOPRAZOLE	Concomitant	NOT SPECIFIED					
SOMATULINE AUTOGEL PRE-FILLED SYRINGE	Suspect	SOLUTION (EXTENDED RELEASE)	Subcutaneous	120.0 Milligram	every 1 Months		Neuroendocrine tumour
SYNTHROID	Concomitant	NOT SPECIFIED					
XARELTO	Concomitant	Coated tablet					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal distension	v.24.1	
Abdominal pain	v.24.1	1 Days
Abdominal rigidity	v.24.1	
Asthenia	v.24.1	
Back pain	v.24.1	4 Days
Bone contusion	v.24.1	
Decreased appetite	v.24.1	
Diarrhoea	v.24.1	
Drug ineffective	v.24.1	
Face injury	v.24.1	
Face injury	v.24.1	
Fall	v.24.1	1 Days
Fall	v.24.1	
Fall	v.24.1	1 Days
Fatigue	v.24.1	
Flatulence	v.24.1	
General physical health deterioration	v.24.1	
Hypersomnia	v.24.1	
Injury	v.24.1	
Mastication disorder	v.24.1	
Neoplasm progression	v.24.1	
Oedema peripheral	v.24.1	1 Days
Pleurisy	v.24.1	
Product dose omission issue	v.24.1	
Pyrexia	v.24.1	
Restlessness	v.24.1	
Swelling face	v.24.1	
Terminal state	v.24.1	
Urinary tract infection	v.24.1	4 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03928930	2	2021-03-23	2021-05-26	MAH	2021259802	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
30 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BOTULINUM TOXIN TYPE A	Concomitant						Migraine
CIMZIA	Concomitant	Solution for injection		1.0 Dosage forms			Arthritis
DESVENLAFAXINE SUCCINATE	Concomitant						Depression
HYDROXYCHLOROQUINE SULFATE	Concomitant						Arthritis
LIOTHYRONINE SODIUM	Concomitant						Arthralgia
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Back pain	v.24.1	
Fatigue	v.24.1	
Muscular weakness	v.24.1	
Paraesthesia	v.24.1	
Sensory disturbance	v.24.1	
Urinary incontinence	v.24.1	-52

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03929475	0	2021-03-23	2021-03-23	MAH	2021311572	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
48 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03929479	2	2021-03-23	2021-05-11	MAH	2021298677	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
60 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AMLODIPINE	Concomitant	Tablets		2.5 Milligram	every 1 Days		Hypertension
EZETIMIBE	Concomitant	Tablets					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Total	1.0 Days	COVID-19 immunisation
PRAVASTATIN	Concomitant				1 every 1 Weeks		Blood cholesterol

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.24.1	
Bronchospasm	v.24.1	
Contusion	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Disease recurrence	v.24.1	
Dysphonia	v.24.1	
Dyspnoea	v.24.1	
Electric shock sensation	v.24.1	1 Months
Fatigue	v.24.1	
Feeling cold	v.24.1	1 Months
Heart rate decreased	v.24.1	
Hyperhidrosis	v.24.1	1 Months
Lethargy	v.24.1	
Loss of personal independence in daily activities	v.24.1	1 Months
Nausea	v.24.1	1 Months
Nervousness	v.24.1	1 Months
Pain	v.24.1	
Peripheral coldness	v.24.1	
Pharyngeal swelling	v.24.1	
Presyncope	v.24.1	
Productive cough	v.24.1	1 Months
Pruritus	v.24.1	
Purpura	v.24.1	
Pyrexia	v.24.1	
Rash pruritic	v.24.1	
Somnolence	v.24.1	1 Months
Throat tightness	v.24.1	1 Months
Urticaria	v.24.1	
Vaccination site pruritus	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03930036	3	2021-03-23	2021-05-24	MAH	2021268849	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
49 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
COVID-19 pneumonia	v.24.1	
Chest discomfort	v.24.1	
Chest pain	v.24.1	
Conjunctivitis	v.24.1	
Cough	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Diarrhoea	v.24.1	
Headache	v.24.1	
Pain	v.24.1	
Vaccination failure	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03930242	1	2021-03-23	2021-04-08	MAH	2021269009	Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
19 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Liver function test increased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03931070	8	2021-03-24	2021-09-15	MAH	1978818	Study	Other health professional

Serious report?
Serious

Death:	No	**Disability:**	No	**Congenital Anomaly:**	No
Life Threatening:	No	**Hospitalization:**	No	**Other Medically Important Conditions:**	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
24 Years	Female		55 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
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Linked	

Record Type	Link AER** Number
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACTEMRA	Suspect	Solution for infusion	Intravenous (not otherwise specified)	480.0 Milligram	1 every 4 Weeks		Rheumatoid arthritis
ACTEMRA	Suspect	NOT SPECIFIED	Intravenous (not otherwise specified)	430.0 Milligram	1 every 4 Weeks	321.0 Days	Rheumatoid arthritis
ACTEMRA	Suspect	Solution for infusion	Intravenous (not otherwise specified)	500.0 Milligram	1 every 4 Weeks		Rheumatoid arthritis
ACTEMRA	Suspect	Solution for injection in pre-filled syringe	Subcutaneous	162.0 Milligram			Rheumatoid arthritis
COVID-19 VACCINE	Suspect		Unknown				Product used for unknown indication
HYDROXYCHLOROQUINE SULFATE	Concomitant						Product used for unknown indication
MOVISSE	Concomitant	Tablets					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anxiety	v.24.1	
Arthralgia	v.24.1	
Cough	v.24.1	
Depression	v.24.1	
Drug ineffective	v.24.1	
Erythema	v.24.1	
Feeling abnormal	v.24.1	
Inflammation	v.24.1	
Influenza	v.24.1	
Nasal congestion	v.24.1	
Nasopharyngitis	v.24.1	
Off label use	v.24.1	
Oropharyngeal pain	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pain	v.24.1	
Rheumatoid arthritis	v.24.1	
Skin swelling	v.24.1	
Weight increased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03933729	0	2021-03-24	2021-03-24	MAH	2021268997	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
57 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Tinnitus	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03933957	0	2021-03-24	2021-03-24	MAH	2021284282	Spontaneous	Consumer/other non health professional

Serious report?
Serious

Death:	No	**Disability:**	No	**Congenital Anomaly:**	No
Life Threatening:	No	**Hospitalization:**	No	**Other Medically Important Conditions:**	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
80 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETYLSALICYLIC ACID	Concomitant						
CILAZAPRIL	Concomitant		Oral				Heart rate decreased
LIPITOR	Concomitant	NOT SPECIFIED	Unknown				
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood urine	v.24.1	
Chromaturia	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Haemorrhage urinary tract	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03933990	1	2021-03-24	2021-05-24	MAH	2021288431	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.24.1	
Drug ineffective	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03934493	0	2021-03-24	2021-03-24	MAH	2021288254	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
72 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Palpitations	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03934890	2	2021-03-24	2021-07-14	MAH	BL-2021-009704	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
73 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular				COVID-19
COVID-19 VACCINE	Suspect	Injection	Intramuscular				COVID-19
ERGOCALCIFEROL	Concomitant		Unknown				Product used for unknown indication
FOLIC ACID	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication
OMEGA 3	Concomitant	Capsule	Unknown				Product used for unknown indication
PROPRANOLOL HYDROCHLORIDE	Concomitant		Unknown				Tremor
SILIQ 2 SINGLE USE PREFILLED SYRINGES	Suspect	Solution for injection	Subcutaneous	210.0 Milligram	1 every 2 Weeks		Psoriasis

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
SILIQ 2 SINGLE USE PREFILLED SYRINGES	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous	210.0 Milligram	1 every 1 Weeks	15.0 Days	Psoriasis
XANTOFYL PALMITATE	Concomitant		Unknown				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Eye haemorrhage	v.24.1	
Myalgia	v.24.1	1 Days
Vaccination site erythema	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03935425	0	2021-03-24	2021-03-24	MAH	2021273647	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
86 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain upper	v.24.1	
Asthenia	v.24.1	
Blood pressure decreased	v.24.1	
Change of bowel habit	v.24.1	
Chills	v.24.1	
Fall	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Malaise	v.24.1	
Somnolence	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03940231	1	2021-03-25	2021-05-11	MAH	2021320187	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
60 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AMLODIPINE	Concomitant	Tablets					Hypertension
OMALIZUMAB	Concomitant	NOT SPECIFIED		300.0 Milligram			Premedication
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Total	1.0 Days	COVID-19 immunisation
PRAVASTATIN	Concomitant				1 every 1 Weeks		Blood cholesterol
PREDNISONE	Concomitant	NOT SPECIFIED	Oral	100.0 Milligram			
PREDNISONE	Concomitant		Oral	100.0 Milligram			
RANITIDINE	Concomitant		Oral	200.0 Milligram			
RANITIDINE	Concomitant		Oral	200.0 Milligram			
RUPATADINE FUMARATE	Concomitant			2.0 Dosage forms	1 every 1 Days		

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
RUPATADINE FUMARATE	Concomitant			2.0 Dosage forms	1 every 1 Days		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.24.1	30 Minutes
Electric shock sensation	v.24.1	30 Minutes
Fatigue	v.24.1	
Headache	v.24.1	
Hypertension	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Lethargy	v.24.1	
Malaise	v.24.1	
Nausea	v.24.1	30 Minutes
Pain	v.24.1	
Presyncope	v.24.1	30 Minutes
Product supply issue	v.24.1	
Somnolence	v.24.1	30 Minutes
Throat tightness	v.24.1	30 Minutes
Vomiting	v.24.1	30 Minutes

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03943306	0	2021-03-26	2021-03-26	MAH	2021290016	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03943391	0	2021-03-26	2021-03-26	MAH	2021294215	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03943392	0	2021-03-26	2021-03-26	MAH	2021294217	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03943406	0	2021-03-26	2021-03-26	MAH	2021294222	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03943441	0	2021-03-26	2021-03-26	MAH	2021294218	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03943455	0	2021-03-26	2021-03-26	MAH	2021294226	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03943598	0	2021-03-26	2021-03-26	MAH	2021284527	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
71 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BETA-CAROTENE/COPPER/RIBOFLAVIN/SELENIUM/TOCOPHERSOLAN/VITAMIN C/ZINC	Concomitant						
ERGOCALCIFEROL	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Atrial fibrillation	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Heart rate increased	v.24.1	
Malaise	v.24.1	1 Months

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03943786	0	2021-03-26	2021-03-26	MAH	2021294220	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03943794	0	2021-03-26	2021-03-26	MAH	2021294216	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03943808	0	2021-03-26	2021-03-26	MAH	2021294214	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03943848	1	2021-03-26	2021-05-23	MAH	2021293650	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
46 Years	Female			Recovered/resolved with sequelae

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ALIGN	Concomitant						
CIPRO [CIPROFLOXACIN HYDROCHLORIDE]	Concomitant						
ETHINYL ESTRADIOL/LEVONORGESTREL	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain	v.24.1	2 Days

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Discomfort	v.24.1	3 Days
Hepatic enzyme increased	v.24.1	
Nausea	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03943899	2	2021-03-26	2021-04-13	MAH	2021300026	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
59 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Uveitis	v.24.1	1 Months
Vitreous detachment	v.24.1	
Vitreous floaters	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03944405	0	2021-03-26	2021-03-26	MAH	2021294227	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03944414	0	2021-03-26	2021-03-26	MAH	2021294212	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03944616	0	2021-03-26	2021-03-26	MAH	2021294225	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03944638	0	2021-03-26	2021-03-26	MAH	2021294213	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03944976	0	2021-03-26	2021-03-26	MAH	2021294219	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown				COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03944982	0	2021-03-26	2021-03-26	MAH	2021294224	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03944987	0	2021-03-26	2021-03-26	MAH	2021294221	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown				COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03945261	1	2021-03-26	2021-05-03	MAH	2021273314	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03945388	1	2021-03-26	2021-05-12	MAH	2021325015	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
66 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
INSULIN	Concomitant	GLOBULES ORAL					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
RIVAROXABAN	Concomitant	Film-coated tablet	Unknown				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Atrial fibrillation	v.24.1	
COVID-19	v.24.1	
Cardiac failure	v.24.1	
Condition aggravated	v.24.1	
Dyspnoea	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypoxia	v.24.1	
Melaena	v.24.1	
Respiratory failure	v.24.1	
Tachypnoea	v.24.1	
Vaccination failure	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03947885	0	2021-03-28	2021-03-28	MAH	2021289573	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
31 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Urticaria	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03950393	0	2021-03-29	2021-03-29	MAH	2021294223	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03950440	1	2021-03-29	2021-04-12	MAH	2021298878	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
11 Months				Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Transmammary		Total	1.0 Days	COVID-19 immunisation
SULFASALAZINE	Concomitant	NOT SPECIFIED	Transmammary	500.0 Milligram	2 every 1 Days		Arthritis
SYNTHROID	Concomitant	NOT SPECIFIED	Transmammary	137.0 Microgram	1 every 1 Days		Hypothyroidism

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Ear infection	v.24.1	
Exposure via breast milk	v.24.1	
Nasopharyngitis	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pyrexia	v.24.1	
Rhinorrhoea	v.24.1	7 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03950722	0	2021-03-29	2021-03-29	MAH	2021294033	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
31 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ESCITALOPRAM	Concomitant	Tablets		10.0 Milligram			
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
TRICYCLINE	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Syncope	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03951509	2	2021-03-29	2021-05-25	MAH	2021284872	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
45 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
HUMIRA	Concomitant	SOLUTION SUBCUTANEOUS					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain upper	v.24.1	-71
Chest pain	v.24.1	-71
Haematemesis	v.24.1	-71

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03955809	0	2021-03-30	2021-03-30	MAH	2021344096	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
85 Years	Female			Recovered/resolved with sequelae

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cerebrovascular accident	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03956366	1	2021-03-30	2021-05-25	MAH	2021298715	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
41 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETAMINOPHEN/OXYCODONE HYDROCHLORIDE/OXYCODONE TEREPHTHALATE	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
QUETIAPINE FUMARATE	Concomitant						
XARELTO	Concomitant	Coated tablet					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03958525	2	2021-03-31	2021-04-19	MAH	2021BI00996216	Study	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
58 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASA	Concomitant	NOT SPECIFIED	Unknown	325.0 Milligram	1 every 2 Days		Product used for unknown indication
AVONEX PREFILLED SYRINGE, PREFILLED AUTOINJECTOR	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	30.0 Microgram	1 every 1 Weeks	17.0 Years	Multiple sclerosis
COVID-19 VACCINE	Suspect		Other				COVID-19 prophylaxis
TECFIDERA	Suspect	Unknown	Unknown	120.0 Milligram	2 every 1 Days	7.0 Days	Multiple sclerosis
TECFIDERA	Suspect	Unknown	Unknown	120.0 Milligram	3 every 1 Days		Multiple sclerosis

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
TECFIDERA	Suspect	CAPSULE, DELAYED RELEASE	Oral	120.0 Milligram	1 every 1 Days	7.0 Days	Multiple sclerosis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Dysphonia	v.24.1	
Faeces discoloured	v.24.1	
Faeces hard	v.24.1	
Feeling hot	v.24.1	
Flatulence	v.24.1	
Flushing	v.24.1	
Gastric disorder	v.24.1	
Gastrooesophageal reflux disease	v.24.1	
Head discomfort	v.24.1	
Headache	v.24.1	
Malaise	v.24.1	
Nausea	v.24.1	
Oropharyngeal pain	v.24.1	
Paraesthesia	v.24.1	
Speech disorder	v.24.1	
Underdose	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03960634	0	2021-03-31	2021-03-31	MAH	2021304526	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
54 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
HYDRODIURIL	Concomitant	Tablets	Oral				Hypertension
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
SYNTHROID	Concomitant	NOT SPECIFIED	Oral				Hypothyroidism

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Rheumatoid arthritis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03960736	0	2021-03-31	2021-03-31	MAH	2021305690	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
23 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CYMBALTA	Concomitant	NOT SPECIFIED					Anxiety
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular			1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.24.1	3 Days
Dysphagia	v.24.1	3 Days
Fatigue	v.24.1	57 Hours
Gastroenteritis viral	v.24.1	1 Days
Loss of consciousness	v.24.1	1 Days

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Oropharyngeal pain	v.24.1	3 Days
Vomiting projectile	v.24.1	1 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03961291	4	2021-03-31	2021-04-14	MAH	2021335549	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
44 Years	Female			Recovered/resolved with sequelae

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Angiopathy	v.24.1	
Arthralgia	v.24.1	
Carotid artery dissection	v.24.1	
Carotid artery thrombosis	v.24.1	
Cerebrovascular accident	v.24.1	
Chills	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	
Feeling abnormal	v.24.1	
Headache	v.24.1	
Migraine	v.24.1	
Musculoskeletal stiffness	v.24.1	
Myalgia	v.24.1	
Nausea	v.24.1	
Necrosis	v.24.1	
Paraesthesia	v.24.1	
Tinnitus	v.24.1	
Transient ischaemic attack	v.24.1	
Vertebral artery dissection	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03961696	0	2021-03-31	2021-03-31	MAH	2021313447	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
86 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASPIRIN [ACETYLSALICYLIC ACID]	Concomitant			81.0 Milligram			
NEXIUM [ESOMEPRAZOLE MAGNESIUM]	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.24.1	
Syncope	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03962061	1	2021-03-31	2021-06-28	MAH	MOD-2021-054818	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
92 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	1.0 Dosage forms			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.24.1	
Dizziness	v.24.1	
Headache	v.24.1	
Illness	v.24.1	
Loss of consciousness	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03965162	1	2021-04-01	2021-05-21	MAH	2326082	Study	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
60 Years	Female		62 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACTEMRA	Suspect	NOT SPECIFIED	Intravenous (not otherwise specified)	216.0 Milligram	1 every 4 Weeks		Rheumatoid arthritis
ACTEMRA	Suspect	Solution for infusion	Intravenous (not otherwise specified)	240.0 Milligram	1 every 4 Weeks		Rheumatoid arthritis

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				Product used for unknown indication
ELTROXIN	Concomitant	Tablets					Product used for unknown indication
FOLIC ACID	Concomitant	NOT SPECIFIED					Product used for unknown indication
METHOTREXATE	Concomitant	NOT SPECIFIED	Intrathecal				Product used for unknown indication
ROSUVASTATIN	Concomitant	NOT SPECIFIED	Subcutaneous				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Allergy to arthropod sting	v.24.1	
Blood pressure diastolic abnormal	v.24.1	
Blood pressure diastolic decreased	v.24.1	
Blood pressure systolic decreased	v.24.1	
Body temperature decreased	v.24.1	
Heart rate increased	v.24.1	
Oxygen saturation decreased	v.24.1	
Pain	v.24.1	
Weight decreased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03965202	3	2021-04-01	2021-05-24	MAH	CA202030218	Study	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
72 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AMOXICILLIN	Concomitant	NOT SPECIFIED	Unknown	500.0 Milligram	3 every 1 Days		Product used for unknown indication
COVID-19 VACCINE	Suspect		Unknown				Prophylaxis
IMMUNOGLOBULIN (HUMAN)	Suspect	Solution for infusion	Subcutaneous	8.0 Gram	1 every 1 Weeks		Secondary immunodeficiency
IMMUNOGLOBULIN (HUMAN)	Suspect		Unknown	6.0 Gram	1 every 1 Weeks		Secondary immunodeficiency

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal discomfort	v.24.1	
Drug ineffective	v.24.1	
Fatigue	v.24.1	
Gait disturbance	v.24.1	
Infection	v.24.1	
Joint swelling	v.24.1	
Malaise	v.24.1	
Pain	v.24.1	
Renal disorder	v.24.1	
Sinusitis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03969029	5	2021-04-02	2021-08-26	MAH	BL-2020-004214	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
83 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ATORVASTATIN	Concomitant	Tablets			1 every 3.5 Days		Product used for unknown indication
BACLOFEN	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication
COVID-19 VACCINE	Suspect		Unknown				Product used for unknown indication
FUROSEMIDE	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication
INDAPAMIDE/PERINDOPRIL ERBUMINE	Concomitant						Product used for unknown indication

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
SILIQ 2 SINGLE USE PREFILLED SYRINGES	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous	210.0 Milligram	1 every 1 Weeks	1.0 Months	Psoriasis
SILIQ 2 SINGLE USE PREFILLED SYRINGES	Suspect	Solution for injection	Subcutaneous	210.0 Milligram	1 every 2 Weeks		Psoriasis
SILIQ 2 SINGLE USE PREFILLED SYRINGES	Suspect	Solution for injection	Subcutaneous	210.0 Milligram	1 every 2 Weeks		Psoriasis
SILIQ 2 SINGLE USE PREFILLED SYRINGES	Suspect	Solution for injection	Subcutaneous	210.0 Milligram	1 every 2 Weeks	3.0 Months	Psoriasis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthritis	v.24.1	-59
Fatigue	v.24.1	
Headache	v.24.1	-59
Infection	v.24.1	
Injection site discharge	v.24.1	
Injection site haemorrhage	v.24.1	
Injection site vesicles	v.24.1	
Limb mass	v.24.1	
Muscular weakness	v.24.1	0
Pain	v.24.1	0
Peripheral swelling	v.24.1	
Pruritus	v.24.1	
Psoriasis	v.24.1	
Psoriatic arthropathy	v.24.1	-59
Somnolence	v.24.1	
Thyroid function test abnormal	v.24.1	0

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03971681	1	2021-04-02	2021-04-13	MAH	2021307424	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
60 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AMLODIPINE	Concomitant	Tablets	Oral	5.0 Milligram	every 1 Days		Hypertension
BISOPROLOL	Concomitant		Oral	5.0 Milligram	every 1 Days		Cardiac disorder
CANDESARTAN	Concomitant		Oral	8.0 Milligram	every 1 Days		Hypertension
PANTOPRAZOLE	Concomitant	NOT SPECIFIED	Oral	40.0 Milligram	every 1 Days	4.0 Years	Gastrooesophageal reflux disease
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
RAPAFLO	Concomitant	NOT SPECIFIED		8.0 Milligram			
ROSUVASTATIN	Concomitant	NOT SPECIFIED	Oral	5.0 Milligram			Hypercholesterolaemia

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
XARELTO	Concomitant	Coated tablet	Oral	2.5 Milligram	2 every 1 Days		Cardiac disorder

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.24.1	0
Colitis ulcerative	v.24.1	
Disease recurrence	v.24.1	
Disease recurrence	v.24.1	
Gastric ulcer	v.24.1	
Hiatus hernia	v.24.1	
Oesophagitis	v.24.1	
Palpitations	v.24.1	0
Pyrexia	v.24.1	0

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03978381	4	2021-04-06	2021-06-22	MAH	CA2021AMR072582	Study	Consumer/other non health professional

Serious report?
Serious

Death:	No	**Disability:**	No	**Congenital Anomaly:**	No
Life Threatening:	No	**Hospitalization:**	Yes	**Other Medically Important Conditions:**	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
70 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	
Linked	
Linked	
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				COVID-19 prophylaxis
MEPOLIZUMAB	Suspect		Subcutaneous	100.0 Milligram			Asthma
MEPOLIZUMAB	Suspect	Solution for injection in pre-filled syringe	Subcutaneous	100.0 Milligram			Asthma

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bladder pain	v.24.1	
Cystitis	v.24.1	
Pleural effusion	v.24.1	
Pneumonia	v.24.1	
Weight decreased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03979773	0	2021-04-06	2021-04-06	MAH	2021312720	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
35 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Months	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abortion spontaneous	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03979848	1	2021-04-06	2021-06-08	MAH	2021330623	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
94 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
XELJANZ XR	Concomitant	TABLET (EXTENDED-RELEASE)	Oral	11.0 Milligram	every 1 Days		Rheumatoid arthritis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fall	v.24.1	
Impaired quality of life	v.24.1	
Pain	v.24.1	
Rib fracture	v.24.1	
Skin laceration	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03980068	1	2021-04-06	2021-04-12	MAH	2021324356	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
79 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ATACAND	Concomitant	Tablets		2.0 Milligram			
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
SYNTHROID	Concomitant	NOT SPECIFIED					
VARICELLA ZOSTER VACCINE LIVE	Concomitant					1.0 Days	
VITAMIN D	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Feeling abnormal	v.24.1	2 Days

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.24.1	
Nausea	v.24.1	
Pain in jaw	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03980279	3	2021-04-06	2021-05-26	MAH	2021318403	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
27 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Multiple sclerosis	v.24.1	
Neurological symptom	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information

***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03980659	1	2021-04-06	2021-05-25	MAH	2021320713	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
56 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Facial paralysis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03983427	2	2021-04-07	2021-05-04	MAH	CA2021073043	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CLONAZEPAM	Suspect	Tablets	Unknown				Product used for unknown indication
ELTROXIN	Suspect	Tablets	Unknown				Product used for unknown indication
FLUTICASONE PROPIONATE/SALMETEROL XINAFOATE	Suspect		Unknown				Product used for unknown indication
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Epilepsy	v.24.1	
Headache	v.24.1	
Pain	v.24.1	
Paraesthesia	v.24.1	
Seizure	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03985806	1	2021-04-07	2021-06-17	MAH	2021349461	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
23 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dermatitis	v.24.1	
Erythema	v.24.1	
Hyperaesthesia	v.24.1	
Pruritus	v.24.1	
Urticaria	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03986299	3	2021-04-07	2021-05-21	MAH	2021361855	Spontaneous	Consumer/other non health professional

Serious report?	Death:	Disability:	Congenital Anomaly:
Serious	Yes	No	No
	Life Threatening: No	**Hospitalization:** No	**Other Medically Important Conditions:** No

Patient Information

Age	Gender	Height	Weight	Report Outcome
89 Years	Male			Fatal

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
APO-LEVOCARB	Concomitant	Tablets					
FINASTERIDE	Concomitant	Tablets					
LOPERAMIDE HYDROCHLORIDE	Concomitant						Diarrhoea
MIRTAZAPINE	Concomitant						
PANTOPRAZOLE	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
TAMSULOSIN	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cerebrovascular accident	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03986340	1	2021-04-07	2021-04-13	MAH	2021361191	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
47 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
NAPROXEN SODIUM	Concomitant			500.0 Milligram	As required		Pain
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.24.1	
Anaphylactic shock	v.24.1	
Fatigue	v.24.1	
Headache	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03991198	14	2021-04-08	2021-09-20	MAH	CA201908491	Study	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
58 Years	Female		86 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETAMINOPHEN/CODEINE PHOSPHATE	Concomitant		Unknown				
AMITRIPTYLINE	Concomitant		Unknown				
ASA	Concomitant	NOT SPECIFIED	Unknown				
ATORVASTATIN	Concomitant	Tablets	Unknown				
BECLOMETHASONE	Concomitant		Unknown				
BETAMETHASONE DIPROPIONATE	Concomitant	NOT SPECIFIED	Unknown				
BISOPROLOL	Concomitant	Tablets	Unknown				
BUDESONIDE/FORMOTEROL FUMARATE	Concomitant		Unknown				
COVID-19 VACCINE	Suspect		Unknown				Product used for unknown indication

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CYANOCOBALAMIN	Concomitant		Unknown				
D-ALPHA TOCOPHEROL	Concomitant		Unknown				
ERGOCALCIFEROL	Concomitant		Unknown				
FOLIC ACID	Concomitant	NOT SPECIFIED	Unknown				
GABAPENTIN	Concomitant	NOT SPECIFIED	Unknown				
HYDROCHLOROTHIAZIDE	Concomitant	Tablets	Unknown				
LASIX	Concomitant	NOT SPECIFIED	Oral	40.0 Milligram	2 every 1 Days		Diuretic therapy
LIPITOR	Concomitant	NOT SPECIFIED	Unknown				
LOSARTAN	Concomitant		Unknown				
MAGNESIUM	Concomitant	NOT SPECIFIED	Unknown				
METFORMIN	Concomitant		Unknown				
METOCLOPRAMIDE HYDROCHLORIDE	Concomitant		Unknown				
MOMETASONE FUROATE	Concomitant		Unknown				
RAMIPRIL	Concomitant	NOT SPECIFIED	Unknown				
RANITIDINE	Concomitant		Unknown				
REPLAGAL SINGLE-USE VIAL	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	17.5 Milligram	1 every 2 Weeks		Fabry's disease
REPLAGAL SINGLE-USE VIAL	Suspect	Concentrate for solution for infusion	Unknown		1 every 2 Weeks		Fabry's disease
REPLAGAL SINGLE-USE VIAL	Suspect	Concentrate for solution for infusion	Unknown	21.0 Milligram	1 every 2 Weeks		Fabry's disease
REPLAGAL SINGLE-USE VIAL	Suspect	Concentrate for solution for infusion	Unknown	5.0 Dosage forms	1 every 2 Weeks		Fabry's disease
REPLAGAL SINGLE-USE VIAL	Suspect	Concentrate for solution for infusion	Unknown	5.0 Dosage forms	1 every 2 Weeks		Fabry's disease
REPLAGAL SINGLE-USE VIAL	Suspect	Concentrate for solution for infusion	Unknown	6.0 Dosage forms	1 every 2 Weeks		Fabry's disease
REPLAGAL SINGLE-USE VIAL	Suspect	Concentrate for solution for infusion	Unknown	6.0 Milligram	1 every 2 Weeks		Fabry's disease
TECTA	Concomitant	NOT SPECIFIED	Unknown				
TRAMADOL	Concomitant		Unknown				
VITAMIN D	Concomitant	NOT SPECIFIED	Unknown				
ZOPICLONE	Concomitant		Unknown				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Asthenia	v.24.1	
Atrial fibrillation	v.24.1	
Blood pressure decreased	v.24.1	
Blood pressure increased	v.24.1	
C-reactive protein increased	v.24.1	
COVID-19 immunisation	v.24.1	
Cardiac disorder	v.24.1	
Cardiac flutter	v.24.1	
Diarrhoea	v.24.1	
Fall	v.24.1	
Fatigue	v.24.1	
Flushing	v.24.1	
Heart rate decreased	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Lung disorder	v.24.1	
Malaise	v.24.1	
Pericardial effusion	v.24.1	
Pleural effusion	v.24.1	
Pneumonia	v.24.1	
Poor venous access	v.24.1	
Pyrexia	v.24.1	
Respiratory rate increased	v.24.1	
Underdose	v.24.1	
Vein collapse	v.24.1	
Weight decreased	v.24.1	
White blood cell count increased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03991772	2	2021-04-08	2021-06-17	MAH	2021364489	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
91 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CLOPIDOGREL	Concomitant	Tablets					Dizziness, Anticoagulant therapy
ELIQUIS FILM COATED	Concomitant	Tablets					Cardiovascular disorder
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
PRAVASTATIN	Concomitant						Blood cholesterol abnormal

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Dyspnoea	v.24.1	7 Days
Herpes zoster	v.24.1	2 Months
Insomnia	v.24.1	7 Days
Pain	v.24.1	7 Days
Rash	v.24.1	7 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03991894	1	2021-04-08	2021-04-20	MAH	2021335886	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
76 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bell's palsy	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03991904	1	2021-04-08	2021-04-08	MAH	2021359931	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
32 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.24.1	
Nausea	v.24.1	
Pyrexia	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03991991	3	2021-04-08	2021-04-30	MAH	2021375885	Spontaneous	Other health professional

Serious report?	Death:	Disability:	Congenital Anomaly:
Serious	Yes	No	No
	Life Threatening: No	**Hospitalization:** No	**Other Medically Important Conditions:** No

Patient Information

Age	Gender	Height	Weight	Report Outcome
85 Years	Male			Fatal

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Diarrhoea	v.24.1	
Myocardial infarction	v.24.1	
Nausea	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03992430	1	2021-04-08	2021-04-28	MAH	2021336042	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
37 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
DYMISTA SUSPENSION	Concomitant	SPRAY, METERED DOSE	Intra-nasal		2 every 1 Days		Upper-airway cough syndrome
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dyspnoea	v.24.1	
Fluid retention	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03992468	0	2021-04-08	2021-04-08	MAH	2021353502	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
67 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACLIDINIUM BROMIDE/FORMOTEROL FUMARATE	Concomitant			400.0 Microgram			Chronic obstructive pulmonary disease
OCRELIZUMAB	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Decreased appetite	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fall	v.24.1	
Headache	v.24.1	
Malaise	v.24.1	
Monoparesis	v.24.1	
Pain	v.24.1	
Pain in extremity	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03997230	2	2021-04-09	2021-07-07	MAH	2021338214	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
35 Years	Female	165 Centimeter	54 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_04004953

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ELAGOLIX SODIUM	Concomitant		Oral				Endometriosis
ESOMEPRAZOLE SODIUM	Concomitant		Oral				Gastrooesophageal reflux disease
NORLUTATE	Concomitant	Tablets	Oral				Endometriosis
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.24.1	
Hypertension	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypoaesthesia	v.24.1	
Myocarditis	v.24.1	
Troponin increased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03997331	2	2021-04-09	2021-06-17	MAH	2021338176	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
70 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
VITAMIN D	Concomitant		Oral				Prophylaxis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.24.1	
Dizziness	v.24.1	
Feeling abnormal	v.24.1	
Feeling of body temperature change	v.24.1	
Loss of consciousness	v.24.1	
Malaise	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Nausea	v.24.1	
Pyrexia	v.24.1	
Sedation	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_03997709	2	2021-04-09	2021-04-21	MAH	2021376543	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
52 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Deep vein thrombosis	v.24.1	
Heavy menstrual bleeding	v.24.1	
Joint swelling	v.24.1	
Pain	v.24.1	
Thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04003027	1	2021-04-12	2021-05-06	MAH	2021M1018991	Published	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
51 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Duplicate	E2B_03903049

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CLOZAPINE	Suspect		Unknown	150.0 Milligram			Schizoaffective disorder
CLOZAPINE	Suspect		Unknown	500.0 Milligram	1 every 1 Days	10.0 Years	Schizoaffective disorder
CLOZAPINE	Suspect		Unknown	300.0 Milligram	1 every 1 Days		Schizoaffective disorder
DIVALPROEX SODIUM	Suspect	NOT SPECIFIED	Unknown				Product used for unknown indication
FENOFIBRATE	Suspect	NOT SPECIFIED	Unknown				Product used for unknown indication
LINAGLIPTIN	Suspect		Unknown				Product used for unknown indication

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
METFORMIN	Suspect		Unknown				Product used for unknown indication
PANTOPRAZOLE	Suspect		Unknown				Product used for unknown indication
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown				Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Affect lability	v.24.1	
Antipsychotic drug level increased	v.24.1	
Atelectasis	v.24.1	
C-reactive protein increased	v.24.1	
Delirium	v.24.1	
Drug interaction	v.24.1	
Drug level increased	v.24.1	
Fall	v.24.1	
Hydrocephalus	v.24.1	
Incontinence	v.24.1	
Lymphocyte count decreased	v.24.1	
Monocyte count increased	v.24.1	
Neutrophil count increased	v.24.1	
Pneumonia	v.24.1	
Sedation complication	v.24.1	
Toxicity to various agents	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04004766	1	2021-04-12	2021-05-26	MAH	2021345208	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
84 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ATORVASTATIN	Concomitant						
CANDESARTAN	Concomitant						Hypertension
CLOPIDOGREL BISULFATE	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bell's palsy	v.24.1	
Eyelid disorder	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04004905	1	2021-04-12	2021-04-21	MAH	2021345648	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
76 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dysuria	v.24.1	1 Days
Haemorrhage urinary tract	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information

***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04005035	1	2021-04-12	2021-04-20	MAH	2021344703	Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
78 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AMLODIPINE	Concomitant	Tablets	Oral	5.0 Milligram	every 1 Days		Blood pressure measurement
CANDESARTAN	Concomitant		Oral	8.0 Milligram	2 every 1 Days		Blood pressure measurement
ELIQUIS FILM COATED	Concomitant	Tablets	Oral	5.0 Milligram	2 every 1 Days		Arrhythmia
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total		COVID-19 immunisation
PROPAFENONE	Concomitant		Oral	150.0 Milligram	2 every 1 Days		Arrhythmia

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Back pain	v.24.1	
Neck pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04005244	1	2021-04-12	2021-05-26	MAH	2021344936	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
70 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
ROSUVASTATIN	Concomitant	NOT SPECIFIED					
VALSARTAN	Concomitant	NOT SPECIFIED					
VITAMIN D	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Deafness	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04009772	2	2021-04-13	2021-04-29	MAH	2021364881	Spontaneous	Physician

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
82 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blindness	v.24.1	
Cerebral infarction	v.24.1	
Cognitive disorder	v.24.1	
Confusional state	v.24.1	
Delirium	v.24.1	
Facial paralysis	v.24.1	
Fall	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Feeling abnormal	v.24.1	
Hemiparesis	v.24.1	
Ischaemic stroke	v.24.1	
Paralysis	v.24.1	
Prostatomegaly	v.24.1	
Renal disorder	v.24.1	
Scratch	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04009844	0	2021-04-13	2021-04-13	MAH	2021353528	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
51 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CANAGLIFLOZIN HEMIHYDRATE	Concomitant		Oral				Type 2 diabetes mellitus
JANUVIA	Concomitant	NOT SPECIFIED	Unknown				
METFORMIN	Concomitant						Diabetes mellitus
METFORMIN HYDROCHLORIDE/SITAGLIPTIN PHOSPHATE MONOHYDRATE	Concomitant		Oral				Type 2 diabetes mellitus
OLMESARTAN [OLMESARTAN MEDOXOMIL]	Concomitant		Oral	20.0 Milligram			Blood pressure abnormal

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular			1.0 Days	COVID-19 immunisation
ROSUVASTATIN CALCIUM	Concomitant		Oral				Hypercholesterolaemia

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bell's palsy	v.24.1	
Muscle twitching	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04010459	1	2021-04-13	2021-07-12	MAH	2021350285	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
70 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETYLSALICYLIC ACID	Concomitant			80.0 Milligram			
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
QUETIAPINE	Concomitant	Tablets		25.0 Milligram			
SYNTHROID	Concomitant	NOT SPECIFIED		0.05 Milligram			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Angioedema	v.24.1	
Chills	v.24.1	
Dysgeusia	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.24.1	
Lip swelling	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04010481	5	2021-04-13	2021-08-27	MAH	2021358791	Published	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
51 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Duplicate	E2B_03903049

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CLOZAPINE	Suspect	Tablets	Unknown	300.0 Milligram	1 every 1 Days		Schizoaffective disorder
FENOFIBRATE	Concomitant	NOT SPECIFIED					
LINAGLIPTIN	Concomitant						
METFORMIN	Concomitant						
PANTOPRAZOLE	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation
VALPROATE SEMISODIUM	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Condition aggravated	v.24.1	
Delirium	v.24.1	
Drug interaction	v.24.1	
Drug level increased	v.24.1	
Fall	v.24.1	
Incontinence	v.24.1	
Toxicity to various agents	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04013913	1	2021-04-14	2021-04-21	MAH	2021366347	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
79 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BISOPROLOL	Concomitant		Oral				Hypertension
DIOVAN	Concomitant	NOT SPECIFIED	Oral				Hypertension
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.24.1	6 Hours
Myalgia	v.24.1	1 Days
Nausea	v.24.1	6 Hours

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04014144	1	2021-04-14	2021-04-21	MAH	2021386482	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
99 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BISOPROLOL	Concomitant		Oral		1 every 1 Days		Hypertension
LYRICA	Concomitant	Capsules	Oral				Sciatica
MAGNESIUM	Concomitant	NOT SPECIFIED	Oral		1 every 1 Days		Supplementation therapy
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain upper	v.24.1	
Asthenia	v.24.1	2 Days

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Gastric ulcer	v.24.1	
Influenza like illness	v.24.1	
Pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04014879	0	2021-04-14	2021-04-14	MAH	2021391662	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
49 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BUPROPION HCL XL	Concomitant	TABLET (EXTENDED-RELEASE)		150.0 Milligram	1 every 1 Days		
ELAGOLIX SODIUM	Concomitant			150.0 Milligram	1 every 1 Days		Menopausal symptoms
PANTOPRAZOLE	Concomitant	NOT SPECIFIED		40.0 Milligram	1 every 1 Days		
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
VENLAFAXINE HYDROCHLORIDE	Concomitant			150.0 Milligram	2 every 1 Days		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cold sweat	v.24.1	
Condition aggravated	v.24.1	
Fatigue	v.24.1	
Gait disturbance	v.24.1	
Headache	v.24.1	
Hot flush	v.24.1	
Inflammation	v.24.1	
Joint swelling	v.24.1	
Musculoskeletal stiffness	v.24.1	
Nausea	v.24.1	
Pain	v.24.1	
Pruritus	v.24.1	
Skin reaction	v.24.1	1 Days
Tendonitis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04014886	2	2021-04-14	2021-06-08	MAH	2021381777	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Transplacental		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Foetal growth restriction	v.24.1	
Maternal exposure before pregnancy	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04015423	1	2021-04-14	2021-04-22	MAH	2021375448	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
64 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Tinnitus	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04016795	2	2021-04-15	2021-07-20	MAH	MOD-2021-071226	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
30 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BETA-CAROTENE/CALCIUM SULFATE/D-ALPHA TOCOPHERYL ACETATE/FERROUS FUMARATE/FOLIC ACID/NICOTINAMIDE/PYRIDOXINE HYDROCHLORIDE/RIBOFLAVIN/THIAMINE MONONITRATE/VITAMIN A ACETATE/VITAMIN B12/VITAMIN C/VITAMIN D3/ZINC OXIDE	Concomitant						Product used for unknown indication
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	1.0 Dosage forms			COVID-19 immunisation

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
INSULIN	Concomitant	GLOBULES ORAL					Product used for unknown indication
IRON	Concomitant						Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Haemorrhage in pregnancy	v.24.1	
Maternal exposure during pregnancy	v.24.1	1 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04018405	2	2021-04-15	2021-08-20	MAH	2021366264	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
41 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.24.1	
Drug ineffective	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

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Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04018652	1	2021-04-15	2021-04-26	MAH	2021365380	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
76 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ALPRAZOLAM	Concomitant	Tablets					
IRBESARTAN	Concomitant	Tablets					
PANTOLOC [PANTOPRAZOLE]	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
ROSUVASTATIN CALCIUM	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.24.1	
Decreased appetite	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Disturbance in attention	v.24.1	
Dizziness	v.24.1	
Fatigue	v.24.1	
Hypersomnia	v.24.1	
Loss of consciousness	v.24.1	1 Days
Pain	v.24.1	
Pneumonia	v.24.1	
Pyrexia	v.24.1	
Syncope	v.24.1	1 Days
Thirst	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04018684	4	2021-04-15	2021-06-21	MAH	2021377018	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
80 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BETA-CAROTENE/BIOTIN/CALCIUM/CHROMIUM/COPPER/FOLIC ACID/IODINE/IRON/MAGNESIUM/MANGANESE/MOLYBDENUM/NICOTINIC ACID/PANTOTHENIC ACID/PHOSPHORUS/PYRIDOXINE HYDROCHLORIDE/RIBOFLAVIN/SELENIUM/THIAMINE/VITAMIN A/VITAMIN B12/VITAMIN C/VITAMIN D/VITAMIN E	Concomitant						
FINASTERIDE	Concomitant	Tablets		5.0 Milligram			

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
VITAMIN D3	Concomitant	Capsules					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dry throat	v.24.1	
Fatigue	v.24.1	
Lack of spontaneous speech	v.24.1	
Loss of consciousness	v.24.1	
Memory impairment	v.24.1	
Pain	v.24.1	
Respiratory failure	v.24.1	
Road traffic accident	v.24.1	
Somnolence	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

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Report Information

***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04019649	2	2021-04-15	2021-05-12	MAH	2021364577	Spontaneous	Physician

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
70 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ALLOPURINOL	Concomitant	Tablets	Oral	200.0 Milligram	every 1 Days		
ATORVASTATIN	Concomitant	Tablets	Oral	40.0 Milligram	every 1 Days		Blood cholesterol
CARBAMAZEPINE	Concomitant	NOT SPECIFIED	Oral	200.0 Milligram	every 1 Days		Epilepsy
COLCHICINE	Concomitant	Tablets		1.0 Dosage forms	1 every 2 Days		Gout
IRBESARTAN HCT	Concomitant	Tablets	Oral		every 1 Days		
MYRBETRIQ	Concomitant	TABLET (EXTENDED-RELEASE)		50.0 Milligram	every 1 Days		
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
TAMSULOSIN	Concomitant	NOT SPECIFIED		0.4 Milligram	every 1 Days		Dysuria

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Alanine aminotransferase increased	v.24.1	
Blood cholesterol decreased	v.24.1	
Dysstasia	v.24.1	
Haematocrit decreased	v.24.1	
Haemoglobin decreased	v.24.1	
Hemiparesis	v.24.1	
Hyperuricaemia	v.24.1	
Hypoaesthesia	v.24.1	
Lymphocyte count decreased	v.24.1	
Mean cell haemoglobin	v.24.1	
Mean cell volume increased	v.24.1	
Monocyte count increased	v.24.1	
Myelocyte count increased	v.24.1	
Peripheral arterial occlusive disease	v.24.1	
Platelet count decreased	v.24.1	
Red blood cell count decreased	v.24.1	
Shoulder injury related to vaccine administration	v.24.1	
Vaccination site pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

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Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04023630	1	2021-04-16	2021-06-25	MAH	2021366654	Spontaneous	Physician

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
76 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Drug hypersensitivity	v.24.1	
Erythema	v.24.1	
Pruritus	v.24.1	
Swelling face	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
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Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04025655	2	2021-04-16	2021-05-20	MAH	2021257921	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
72 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AMLODIPINE	Concomitant	Tablets	Oral	2.5 Milligram	2 every 1 Days		Hypertension
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
SYNTHROID	Concomitant	NOT SPECIFIED	Oral	0.075 Milligram			Hypothyroidism
VITAMIN D	Concomitant	NOT SPECIFIED	Oral	10000.0 IU (International Unit)	1 every 1 Weeks		Supplementation therapy

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Condition aggravated	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Disease recurrence	v.24.1	
Dizziness	v.24.1	-72
Fatigue	v.24.1	
Hypersensitivity	v.24.1	
Hypertension	v.24.1	
Migraine	v.24.1	-72
Nausea	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
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Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04027567	2	2021-04-18	2021-09-03	MAH	2021A283389	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
65 Years	Male	172 Centimeter	70 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.5 ml		1.0 Days	COVID-19 immunisation
ERGOCALCIFEROL	Concomitant	NOT SPECIFIED	Unknown				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Tinnitus	v.24.1	2 Weeks

Canada Vigilance
Summary of Reported Adverse Reactions

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Total Number of Reports:	637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04030625	0	2021-04-19	2021-04-19	MAH	A202103796	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
50 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular				COVID-19 immunisation
PREDNISONE	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication
SOLIRIS SINGLE USE, 300 MG/30ML	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)		1 every 2 Weeks		Neuromyelitis optica spectrum disorder

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Depression	v.24.1	
Fatigue	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Feeling abnormal	v.24.1	
Headache	v.24.1	
Multiple fractures	v.24.1	
Musculoskeletal stiffness	v.24.1	
Pain in extremity	v.24.1	
Pelvic fracture	v.24.1	
Upper limb fracture	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

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Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04031148	1	2021-04-19	2021-08-12	MAH	2021A280719	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
63 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Vocal cord disorder	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

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Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04032343	0	2021-04-19	2021-04-19	MAH	2021384027	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
74 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				Product used for unknown indication
HYDROXYCHLOROQUINE	Concomitant		Unknown	400.0 Milligram	1 every 1 Days		
METHOTREXATE	Suspect		Unknown	25.0 Milligram	1 every 1 Weeks		Product used for unknown indication
XELJANZ	Suspect	Tablet	Oral	5.0 Milligram	2 every 1 Days		Psoriatic arthropathy

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Condition aggravated	v.24.1	-93

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Therapeutic product effect incomplete	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

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Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04032530	0	2021-04-19	2021-04-19	MAH	2021387407	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
87 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ERGOCALCIFEROL	Concomitant		Oral	10000.0 IU (International Unit)	1 every 1 Weeks		Supplementation therapy
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
SYNTHROID	Concomitant	NOT SPECIFIED	Oral	0.1 Milligram	every 1 Days		Hypothyroidism

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Myalgia	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pallor	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

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Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04032538	0	2021-04-19	2021-04-19	MAH	2021391595	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
91 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Seizure	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

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Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04032649	0	2021-04-19	2021-04-19	MAH	2021400051	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
78 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ALTACE	Concomitant	Capsules	Oral	5.0 Milligram			Hypertension
APO-HYDROCHLOROTHIAZIDE	Concomitant	Tablets	Oral	12.5 Milligram			Diuretic therapy
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Condition aggravated	v.24.1	
Herpes zoster oticus	v.24.1	
Hypoaesthesia	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pain in extremity	v.24.1	810 Minutes
Paraesthesia	v.24.1	

Canada Vigilance
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Initial Received Date:	2021-01-01 to 2021-04-30
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Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04032713	2	2021-04-19	2021-05-17	MAH	2021377088	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
69 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETYLSALICYLIC ACID	Concomitant			81.0 Milligram	every 1 Days		Prophylaxis
ALVESCO	Concomitant	AEROSOL, METERED DOSE	Inhalation	1.0 Dosage forms	2 every 1 Days		Asthma
BRILINTA	Concomitant			60.0 Milligram	2 every 1 Days		Thrombosis prophylaxis
CANDESARTAN	Concomitant			16.0 Milligram	every 1 Days		Blood pressure measurement
DILTIAZEM	Concomitant			180.0 Milligram	every 1 Days		Blood pressure measurement
PANTOLOC [PANTOPRAZOLE]	Concomitant			40.0 Milligram	2 every 1 Days		Gastrooesophageal reflux prophylaxis

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
PMS-AZITHROMYCIN	Concomitant	NOT SPECIFIED		500.0 Milligram			Bronchiectasis
ROSUVASTATIN	Concomitant	NOT SPECIFIED		20.0 Milligram	every 1 Days		Hypercholesterolaemia
SINGULAIR	Concomitant	NOT SPECIFIED		10.0 Milligram	every 1 Days		Asthma
VENTOLIN [SALBUTAMOL SULFATE]	Concomitant		Inhalation		As required		Asthma

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.24.1	
Depressed level of consciousness	v.24.1	
Heart rate decreased	v.24.1	
Syncope	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04037301	0	2021-04-20	2021-04-20	MAH	2021400105	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
73 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
D-ALPHA TOCOPHEROL/DOCOSAHEXAENOIC ACID/EICOSAPENTAENOIC ACID	Concomitant		Oral	1.0 Gram	1 every 1 Days		Supplementation therapy
ERGOCALCIFEROL	Concomitant		Oral	1.0 Gram			Supplementation therapy
MAGNESIUM	Concomitant	NOT SPECIFIED	Oral		1 every 1 Days		Muscle spasms
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypoaesthesia	v.24.1	1914 Minutes
Paraesthesia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04037317	0	2021-04-20	2021-04-20	MAH	2021376955	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
53 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest discomfort	v.24.1	
Chills	v.24.1	
Dyspnoea	v.24.1	
Fatigue	v.24.1	
Headache	v.24.1	
Influenza like illness	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pericardial effusion	v.24.1	
Pleural effusion	v.24.1	
Pyrexia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information

***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04037330	0	2021-04-20	2021-04-20	MAH	2021391366	Spontaneous	Consumer/other non health professional

Serious report?
Serious

Death:	No	**Disability:**	No	**Congenital Anomaly:**	No
Life Threatening:	No	**Hospitalization:**	No	**Other Medically Important Conditions:**	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
70 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASA	Concomitant	NOT SPECIFIED	Oral				Blood disorder
DUTASTERIDE	Concomitant	Capsules	Oral	0.5 Milligram	1 every 2 Days		Prostatomegaly
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
ROSUVASTATIN	Concomitant	NOT SPECIFIED	Oral	10.0 Milligram	1 every 1 Days		Hypercholesterolaemia
TAMSULOSIN	Concomitant	NOT SPECIFIED	Oral	0.4 Milligram	1 every 2 Days		Prostatomegaly
TIMOLOL	Concomitant	NOT SPECIFIED	Ophthalmic	1.0 Gtt	1 every 1 Days		Glaucoma

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bell's palsy	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04037361	0	2021-04-20	2021-04-20	MAH	2021376863	Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
33 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypoaesthesia oral	v.24.1	
Vaccination site discomfort	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04037670	1	2021-04-20	2021-05-28	MAH	2021385471	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
70 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Haemorrhage urinary tract	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04037734	1	2021-04-20	2021-06-11	MAH	2021382936	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
68 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pulmonary embolism	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04037859	1	2021-04-20	2021-06-15	MAH	2021382001	Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
39 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CLOZAPINE	Suspect	Tablets	Unknown				Product used for unknown indication
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
C-reactive protein increased	v.24.1	
Drug interaction	v.24.1	
Drug level increased	v.24.1	
Malaise	v.24.1	
Myocarditis	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Sepsis	v.24.1	
Syncope	v.24.1	
Troponin increased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information

***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04038656	0	2021-04-20	2021-04-20	MAH	2021382773	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
40 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Deafness unilateral	v.24.1	
Dizziness	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04043718	1	2021-04-21	2021-05-04	MAH	2021400103	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
59 Years				Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Angina pectoris	v.24.1	
Arthralgia	v.24.1	2 Days
Condition aggravated	v.24.1	
Fatigue	v.24.1	2 Days
Myalgia	v.24.1	2 Days
Palpitations	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pyrexia	v.24.1	2 Days
Stress	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04043831	3	2021-04-21	2021-07-02	MAH	2021386192	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
40 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CANNABIS SATIVA	Concomitant						Sleep disorder
CETIRIZINE HYDROCHLORIDE	Concomitant		Oral				Chronic sinusitis
ERGOCALCIFEROL	Concomitant						
MAGNESIUM	Concomitant	NOT SPECIFIED					
NAPROXEN	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anxiety	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	2 Weeks
Autoimmune disorder	v.24.1	
Blood pressure fluctuation	v.24.1	
Chest discomfort	v.24.1	22 Days
Chills	v.24.1	1 Days
Circulatory collapse	v.24.1	
Condition aggravated	v.24.1	
Cough	v.24.1	22 Days
Dry eye	v.24.1	2 Months
Dry mouth	v.24.1	2 Months
Dysgeusia	v.24.1	2 Weeks
Erythema	v.24.1	
Eye pain	v.24.1	0
Fatigue	v.24.1	
Headache	v.24.1	83 Days
Irritable bowel syndrome	v.24.1	
Limb injury	v.24.1	
Muscle spasms	v.24.1	
Myalgia	v.24.1	2 Weeks
Nausea	v.24.1	
Night sweats	v.24.1	1 Days
Pain in extremity	v.24.1	
Pyrexia	v.24.1	14 Days
Rash	v.24.1	
Raynaud's phenomenon	v.24.1	
Red blood cell count increased	v.24.1	
Renal disorder	v.24.1	-70
Skin discolouration	v.24.1	
Sleep disorder	v.24.1	
Temperature regulation disorder	v.24.1	
Urinary tract infection	v.24.1	-70
Vascular pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04043905	2	2021-04-21	2021-06-15	MAH	2021387187	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
78 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CANDESARTAN	Concomitant		Oral				Hypertension
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.24.1	
Headache	v.24.1	
Hypoaesthesia	v.24.1	
Malaise	v.24.1	
Musculoskeletal stiffness	v.24.1	
Pain in extremity	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Vertigo	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04044051	1	2021-04-21	2021-05-03	MAH	2021400486	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Syncope	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04044435	2	2021-04-21	2021-07-22	MAH	2021400417	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
66 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETYLSALICYLIC ACID	Concomitant						Factor V Leiden carrier
ADVAIR	Concomitant	NOT SPECIFIED	Inhalation				Chronic obstructive pulmonary disease
DIABETA [GLIBENCLAMIDE]	Concomitant		Oral				Diabetes mellitus
IPRATROPIUM BROMIDE/SALBUTAMOL SULFATE	Concomitant		Inhalation				Chronic obstructive pulmonary disease
METFORMIN	Concomitant		Oral				Diabetes mellitus

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
SEMAGLUTIDE	Concomitant	SOLUTION SUBCUTANEOUS					Diabetes mellitus

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.24.1	
Dyspnoea	v.24.1	
Fatigue	v.24.1	
Headache	v.24.1	
Loss of personal independence in daily activities	v.24.1	
Musculoskeletal stiffness	v.24.1	
Pyrexia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04044601	0	2021-04-21	2021-04-21	MAH	2021387359	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
31 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Blood pressure increased	v.24.1	
Dizziness	v.24.1	
Headache	v.24.1	
Malaise	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04044700	0	2021-04-21	2021-04-21	MAH	2021399997	Spontaneous	Consumer/other non health professional

Serious report?
Serious

Death:	No	**Disability:**	No	**Congenital Anomaly:**	No
Life Threatening:	No	**Hospitalization:**	No	**Other Medically Important Conditions:**	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
62 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ATORVASTATIN	Concomitant	Tablets	Oral	10.0 Milligram	every 1 Days		Hypercholesterolaemia
CLONAZEPAM	Concomitant	Tablets	Oral		As required		Insomnia
COVERSYL [PERINDOPRIL ARGININE]	Concomitant		Oral	8.0 Milligram	every 1 Days		Hypertension
MIRABEGRON	Concomitant		Oral	50.0 Milligram	every 1 Days		Hypertonic bladder
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain upper	v.24.1	2 Days
Cough	v.24.1	
Dysphagia	v.24.1	
Dyspnoea	v.24.1	
Headache	v.24.1	1 Days
Lymphadenopathy	v.24.1	
Myalgia	v.24.1	
Nasal congestion	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04047866	0	2021-04-22	2021-04-22	MAH	2021400086	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
70 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CALCIUM	Concomitant	NOT SPECIFIED	Oral	500.0 Milligram			Supplementation therapy
DARUNAVIR	Concomitant		Oral	600.0 Milligram	2 every 1 Days		HIV infection
ETRAVIRINE	Concomitant		Oral	200.0 Milligram	2 every 1 Days		
HALOPERIDOL	Concomitant	NOT SPECIFIED	Oral	15.0 Milligram	2 every 1 Days		Schizophrenia
MIRTAZAPINE	Concomitant	Tablets	Oral		1 every 1 Days		Depression
OLANZAPINE	Concomitant	NOT SPECIFIED	Oral	25.0 Milligram	1 every 1 Days		Schizophrenia
PANTOPRAZOLE	Concomitant	NOT SPECIFIED	Oral	40.0 Milligram	1 every 1 Days		Gastric disorder
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
PRAZOSIN	Concomitant	Tablets	Oral	1.0 Milligram	1 every 1 Days		Blood pressure management
RALTEGRAVIR	Concomitant		Oral	400.0 Milligram	2 every 1 Days		HIV infection

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
RITONAVIR	Concomitant	NOT SPECIFIED	Oral	100.0 Milligram	2 every 1 Days		HIV infection
ROSUVASTATIN	Concomitant	NOT SPECIFIED	Oral	5.0 Milligram	1 every 1 Days		Hypercholesterolaemia
TAMSULOSIN	Concomitant	NOT SPECIFIED	Oral	0.4 Milligram	1 every 1 Days		Benign prostatic hyperplasia
VARENICLINE TARTRATE	Concomitant		Oral	1.0 Milligram	2 every 1 Days		Smoking cessation therapy

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Alanine aminotransferase increased	v.24.1	12 Days
Aspartate aminotransferase increased	v.24.1	12 Days
Blood creatine phosphokinase increased	v.24.1	12 Days
C-reactive protein increased	v.24.1	12 Days
Haemoglobin decreased	v.24.1	8 Days
Suicidal ideation	v.24.1	14 Days
Vitamin B12 increased	v.24.1	12 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04047994	1	2021-04-22	2021-05-03	MAH	2021400571	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
67 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AMLODIPINE	Concomitant	Tablets	Oral	5.0 Milligram	every 1 Days		Hypertension
ATACAND	Concomitant	Tablets					
MAGNESIUM	Concomitant	NOT SPECIFIED	Oral		1 every 1 Days		Supplementation therapy
OCTREOTIDE	Concomitant	NOT SPECIFIED	Oral	12.5 Milligram	1 every 1 Days		Hypertension
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
VITAMIN D [COLECALCIFEROL]	Concomitant		Oral		1 every 1 Days		Supplementation therapy

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.24.1	1 Hours

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pruritus	v.24.1	
Urticaria	v.24.1	
Vaccination site urticaria	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information

***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04048181	0	2021-04-22	2021-04-22	MAH	2021393430	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
85 Years	Female			Recovered/resolved with sequelae

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BISOPROLOL	Concomitant			10.0 Milligram			
CANDESARTAN	Concomitant			32.0 Milligram			
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation
SITAGLIPTIN	Concomitant			100.0 Milligram			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Transient ischaemic attack	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04048485	0	2021-04-22	2021-04-22	MAH	2021391337	Spontaneous	Consumer/other non health professional

Serious report?
Serious

Death:	No	**Disability:**	No	**Congenital Anomaly:**	No
Life Threatening:	No	**Hospitalization:**	No	**Other Medically Important Conditions:**	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
70 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AMLODIPINE	Concomitant	Tablets	Oral	5.0 Milligram	1 every 1 Days		Hypertension
ASA	Concomitant	NOT SPECIFIED	Oral	80.0 Milligram	1 every 1 Days		Ischaemic stroke
ATORVASTATIN	Concomitant	Tablets	Oral	40.0 Milligram	1 every 1 Days		Hypercholesterolaemia
PERINDOPRIL	Concomitant		Oral	4.0 Milligram	2 every 1 Days		Hypertension
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cerebrovascular accident	v.24.1	
Disturbance in attention	v.24.1	
Dizziness	v.24.1	
Dysarthria	v.24.1	
Fatigue	v.24.1	
Somnolence	v.24.1	
Vision blurred	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04050263	2	2021-04-22	2021-05-10	MAH	2021391606	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
76 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETYLSALICYLIC ACID	Concomitant		Oral				Blood disorder
DILTIAZEM	Concomitant						Nervous system disorder
METFORMIN HYDROCHLORIDE	Concomitant		Oral				Diabetes mellitus
PANTOPRAZOLE	Concomitant	NOT SPECIFIED	Oral				Abdominal discomfort
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total		COVID-19 immunisation
QUETIAPINE FUMARATE	Concomitant		Oral				Nervous system disorder

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
RIVOTRIL	Concomitant	Tablets	Oral				Nervous system disorder

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.24.1	35 Hours
Dysphagia	v.24.1	35 Hours
Dyspnoea	v.24.1	35 Hours
Feeling abnormal	v.24.1	35 Hours
Feeling cold	v.24.1	2 Days
Hypoaesthesia	v.24.1	2 Days
Nausea	v.24.1	35 Hours
Oropharyngeal discomfort	v.24.1	35 Hours
Paralysis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04050308	1	2021-04-22	2021-05-04	MAH	2021400766	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
67 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BUDESONIDE/FORMOTEROL FUMARATE	Concomitant						Chronic obstructive pulmonary disease
DILTIAZEM	Concomitant						Arteriospasm coronary
NITROGLYCERIN	Concomitant	NOT SPECIFIED					Arteriospasm coronary
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
SPIRIVA	Concomitant	NOT SPECIFIED					Chronic obstructive pulmonary disease

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chronic obstructive pulmonary disease	v.24.1	
Cough	v.24.1	
Hypersensitivity	v.24.1	3 Days
Lacrimation increased	v.24.1	3 Days
Productive cough	v.24.1	
Rhinorrhoea	v.24.1	3 Days
Tinnitus	v.24.1	3 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04050331	2	2021-04-22	2021-06-17	MAH	2021395388	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
31 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CIPRALEX [ESCITALOPRAM]	Concomitant						Anxiety
ESCITALOPRAM	Concomitant	Tablets		10.0 Milligram			Anxiety
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
POLYSACCHARIDE-IRON COMPLEX	Concomitant						Blood iron decreased
TRANEXAMIC ACID	Concomitant	NOT SPECIFIED		500.0 Milligram			
VORTIOXETINE HYDROBROMIDE	Concomitant			10.0 Milligram			Anxiety

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Haematochezia	v.24.1	
Rectal haemorrhage	v.24.1	
Rectal polyp	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04050379	1	2021-04-22	2021-06-02	MAH	2021432669	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
65 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
APO-INDAPAMIDE	Concomitant	Tablets		1.25 Milligram			
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
SPIRONOLACTONE	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.24.1	
Fatigue	v.24.1	
Headache	v.24.1	
Hypoaesthesia oral	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Nausea	v.24.1	
Respiratory disorder	v.24.1	
Vaccination site erythema	v.24.1	
Vaccination site pain	v.24.1	
Vaccination site warmth	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04050634	2	2021-04-22	2021-09-13	MAH	2021A335896	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
32 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dyspnoea	v.24.1	
Dyspnoea	v.24.1	
Headache	v.24.1	
Peripheral swelling	v.24.1	
Peripheral swelling	v.24.1	
Pulmonary embolism	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pyrexia	v.24.1	
Pyrexia	v.24.1	
Thrombosis	v.24.1	
Thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04053034	3	2021-04-23	2021-05-24	MAH	2811248	Study	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
78 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETYLSALICYLIC ACID	Concomitant	NOT SPECIFIED	Unknown				
ALLOPURINOL	Concomitant	Tablets					
CANDESARTAN	Concomitant						
CLOPIDOGREL	Concomitant	Tablets					Product used for unknown indication
COVID-19 VACCINE	Suspect		Unknown				Product used for unknown indication
ESBRIET	Suspect	Capsules	Oral	534.0 Milligram	3 every 1 Days	1.0 Days	Idiopathic pulmonary fibrosis
ESBRIET	Suspect	Tablet	Oral	534.0 Milligram	3 every 1 Days		Idiopathic pulmonary fibrosis

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ESBRIET	Suspect		Oral	267.0 Milligram	3 every 1 Days	1.0 Months	Idiopathic pulmonary fibrosis
ESBRIET	Suspect	Capsules	Oral	801.0 Milligram	3 every 1 Days	1.0 Years	Idiopathic pulmonary fibrosis
ESBRIET	Suspect	Tablet	Oral	801.0 Milligram	3 every 1 Days	306.0 Days	Idiopathic pulmonary fibrosis
ESBRIET	Suspect	Tablet	Oral	801.0 Milligram	3 every 1 Days	-31.0	Idiopathic pulmonary fibrosis
ESBRIET	Suspect	Tablet	Oral	801.0 Milligram	2 every 1 Days		Idiopathic pulmonary fibrosis
GLICLAZIDE	Concomitant	Tablets					
LIPITOR	Concomitant	NOT SPECIFIED	Unknown				
METFORMIN HYDROCHLORIDE/SITAGLIPTIN PHOSPHATE MONOHYDRATE	Concomitant						
PANTOPRAZOLE	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal discomfort	v.24.1	
Cardiac failure congestive	v.24.1	
Coronary artery occlusion	v.24.1	
Dyspnoea	v.24.1	
Dyspnoea	v.24.1	
Dyspnoea	v.24.1	
Idiopathic pulmonary fibrosis	v.24.1	
Urine flow decreased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04055142	0	2021-04-23	2021-04-23	MAH	2021416985	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Rheumatoid arthritis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04055205	2	2021-04-23	2021-07-02	MAH	2021393299	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
65 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ERGOCALCIFEROL	Concomitant		Oral				
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
SYNTHROID	Concomitant	NOT SPECIFIED	Oral		1 every 1 Days		Hypothyroidism

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal discomfort	v.24.1	9482 Minutes
Dry mouth	v.24.1	
Dysgeusia	v.24.1	
Dyspnoea	v.24.1	9482 Minutes

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Feeling cold	v.24.1	6 Days
Hypersensitivity	v.24.1	
Malaise	v.24.1	
Palpitations	v.24.1	9482 Minutes
Tachycardia	v.24.1	9482 Minutes
Thirst	v.24.1	
Tremor	v.24.1	9482 Minutes
Troponin increased	v.24.1	1 Months
White coat hypertension	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04060612	1	2021-04-25	2021-05-03	MAH	2021432444	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
72 Years	Female	170 Centimeter		Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.24.1	
Screaming	v.24.1	
Syncope	v.24.1	-72
Vomiting	v.24.1	-72

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04060632	2	2021-04-25	2021-05-07	MAH	2021418643	Spontaneous	Physician

Serious report?	Death:	Disability:	Congenital Anomaly:
Serious	Yes	Yes	No
	Life Threatening: Yes	**Hospitalization:** No	**Other Medically Important Conditions:** Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
73 Years	Male			Fatal

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ENALAPRILAT	Concomitant		Oral	10.0 Milligram	every 1 Days		Blood pressure measurement
HYDROCHLOROTHIAZIDE	Concomitant		Oral	25.0 Milligram	every 1 Days		Blood pressure measurement
NABILONE	Concomitant	NOT SPECIFIED	Oral	0.5 Milligram	every 1 Days		Dementia, Agitation
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
RISPERDAL	Concomitant	NOT SPECIFIED	Oral	2.5 Milligram	every 1 Days		Dementia, Agitation
TRAZODONE	Concomitant		Oral	175.0 Milligram	every 1 Days		Dementia, Agitation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Balance disorder	v.24.1	
Dysphagia	v.24.1	
Gait disturbance	v.24.1	
Ischaemic stroke	v.24.1	
Loss of consciousness	v.24.1	20 Minutes
Nervous system disorder	v.24.1	
Pneumonia aspiration	v.24.1	
Pyrexia	v.24.1	
Seizure	v.24.1	
Sepsis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information

***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04061417	1	2021-04-26	2021-06-28	MAH	MOD-2021-083425	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
55 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BOTULINUM TOXIN TYPE A	Concomitant						Migraine
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	1.0 Dosage forms			COVID-19 immunisation
PROBIOTICS NOS	Concomitant						Product used for unknown indication
VITAMINS NOS	Concomitant						Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cellulitis	v.24.1	
Chills	v.24.1	
Fatigue	v.24.1	
Headache	v.24.1	
Malaise	v.24.1	
Pallor	v.24.1	
Somnolence	v.24.1	
Vaccination site erythema	v.24.1	
Vaccination site pruritus	v.24.1	
Vaccination site swelling	v.24.1	
Vaccination site warmth	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04063186	2	2021-04-26	2021-06-21	MAH	CA2021AMR088851	Study	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
83 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				Product used for unknown indication
MEPOLIZUMAB	Suspect		Subcutaneous	100.0 Milligram			Asthma

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anxiety	v.24.1	
Constipation	v.24.1	
Illness	v.24.1	
Pyrexia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04064304	0	2021-04-26	2021-04-26	MAH	21K-028-3869988-00	Study	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
82 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular			1.0 Months	COVID-19 immunisation
HUMIRA	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous	40.0 Milligram	1 every 2 Weeks		Rheumatoid arthritis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Drug ineffective	v.24.1	
Muscle spasms	v.24.1	0
Muscle spasms	v.24.1	0

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Muscle spasms	v.24.1	0
Musculoskeletal stiffness	v.24.1	0
Pain	v.24.1	0

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04066707	1	2021-04-26	2021-06-07	MAH	2812606	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACTEMRA	Suspect	NOT SPECIFIED	Subcutaneous	163.0 Milligram	1 every 2 Weeks		Rheumatoid arthritis
BISOPROLOL	Concomitant		Unknown				
COVID-19 VACCINE	Suspect		Unknown				Product used for unknown indication
ESCITALOPRAM	Concomitant	Tablets					
FOLIC ACID	Concomitant	NOT SPECIFIED					
JARDIANCE	Concomitant						
LEFLUNOMIDE	Concomitant	NOT SPECIFIED					
LEUCOVORIN [FOLINIC ACID]	Concomitant		Unknown		1 every 1 Weeks		
LEVOTHYROXINE SODIUM	Concomitant	NOT SPECIFIED	Unknown				
MAGNESIUM	Concomitant	NOT SPECIFIED					

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
METFORMIN HYDROCHLORIDE/SITAGLIPTIN PHOSPHATE MONOHYDRATE	Concomitant						
METHOTREXATE	Concomitant	NOT SPECIFIED	Intrathecal				
PREDNISONE	Concomitant	NOT SPECIFIED					
PREGABALIN	Concomitant	Capsules					
RABEPRAZOLE	Concomitant						
RAMIPRIL	Concomitant	NOT SPECIFIED					
RISEDRONATE	Concomitant	Tablets	Unknown		1 every 1 Months		
ROSUVASTATIN	Concomitant	NOT SPECIFIED	Subcutaneous				
VITAMIN D3	Concomitant	Capsules					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	
Gait inability	v.24.1	
Headache	v.24.1	
Hypotension	v.24.1	
Pyrexia	v.24.1	
Thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04066799	0	2021-04-26	2021-04-26	MAH	2021404375	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
59 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arrhythmia	v.24.1	
Feeling abnormal	v.24.1	
Lip disorder	v.24.1	
Lip pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04066819	0	2021-04-26	2021-04-26	MAH	2021404998	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	E2B_04080606

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Months	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.24.1	
Drug ineffective	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04066877	1	2021-04-26	2021-06-08	MAH	2021400771	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
62 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CANDESARTAN	Concomitant						Hypertension
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Balance disorder	v.24.1	
Chills	v.24.1	
Fatigue	v.24.1	
Headache	v.24.1	
Loss of personal independence in daily activities	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Tension headache	v.24.1	
Tinnitus	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04066894	1	2021-04-26	2021-05-04	MAH	2021405821	Spontaneous	Physician

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
84 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BISOPROLOL	Concomitant						
CLOPIDOGREL	Concomitant	Tablets					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
RAMIPRIL	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cerebral artery occlusion	v.24.1	
Cerebrovascular accident	v.24.1	
Disease recurrence	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04066973	0	2021-04-26	2021-04-26	MAH	2021400585	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
78 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Back pain	v.24.1	
Blood pressure decreased	v.24.1	
Cardiac flutter	v.24.1	
Loss of consciousness	v.24.1	
Muscular weakness	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04067221	1	2021-04-26	2021-06-08	MAH	2021401579	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
64 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Diarrhoea	v.24.1	-85
Dizziness	v.24.1	
Fatigue	v.24.1	
Malaise	v.24.1	
Nausea	v.24.1	
Vomiting	v.24.1	-85

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04067314	0	2021-04-26	2021-04-26	MAH	2021405521	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
53 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Paraesthesia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04067325	0	2021-04-26	2021-04-26	MAH	2021417407	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
85 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Bursitis	v.24.1	
Chills	v.24.1	
Night sweats	v.24.1	
Pyrexia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04067402	1	2021-04-26	2021-06-07	MAH	2021432592	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
80 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Atrial fibrillation	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information

***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04067408	1	2021-04-26	2021-06-09	MAH	2021432584	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
80 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Atrial fibrillation	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04067414	3	2021-04-26	2021-06-29	MAH	2021437511	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
84 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Aphasia	v.24.1	
Asthenia	v.24.1	
Bell's palsy	v.24.1	
Chills	v.24.1	
Headache	v.24.1	
Hip fracture	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Lung disorder	v.24.1	
Pyrexia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04067429	0	2021-04-26	2021-04-26	MAH	2021432472	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
66 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
SYNTHROID	Concomitant	NOT SPECIFIED	Oral	0.05 Milligram			Goitre

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dysgeusia	v.24.1	
Erythema	v.24.1	
Headache	v.24.1	1 Days
Hypersensitivity	v.24.1	
Hypoaesthesia	v.24.1	4 Days

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Lip swelling	v.24.1	
Pain in extremity	v.24.1	4 Days
Swelling face	v.24.1	
Vaccination site pain	v.24.1	
Vomiting	v.24.1	1 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04068981	1	2021-04-27	2021-06-16	MAH	MOD-2021-089312	Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
45 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	1.0 Dosage forms			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.24.1	1 Days
Choking	v.24.1	1 Days
Dyspnoea	v.24.1	1 Days
Oropharyngeal discomfort	v.24.1	1 Days
Restlessness	v.24.1	1 Days
Swelling	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04071550	2	2021-04-27	2021-09-02	MAH	20210440264	Study	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
54 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				Product used for unknown indication
REMICADE	Suspect	Solution for infusion	Intravenous (not otherwise specified)	500.0 Milligram	1 every 6 Weeks		Crohn's disease

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
REMICADE	Suspect	POWDER FOR SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	500.0 Milligram			Crohn's disease

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain	v.24.1	
Diarrhoea	v.24.1	
Herpes zoster	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04071579	2	2021-04-27	2021-09-10	MAH	2021A342972	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
62 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.5 ml			Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pulmonary thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04071696	1	2021-04-27	2021-05-18	MAH	2021410599	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
79 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETYLSALICYLIC ACID	Concomitant		Oral	80.0 Milligram			Cardiac disorder, Blood disorder
MINOCYCLINE	Concomitant	NOT SPECIFIED		500.0 Milligram			
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
REPATHA 1 ML SINGLE USE PREFILLED SYRINGE AND AUTOINJECTOR	Concomitant	SOLUTION SUBCUTANEOUS	Oral		1 every 1 Months		Blood cholesterol
TERAZOSIN HYDROCHLORIDE	Concomitant		Oral	5.0 Milligram			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood urine present	v.24.1	7 Days
Haemorrhage urinary tract	v.24.1	7 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04071747	1	2021-04-27	2021-05-18	MAH	2021405410	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
73 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETYLSALICYLIC ACID	Concomitant						
ATORVASTATIN	Concomitant			20.0 Milligram			
EZETIMIBE	Concomitant			10.0 Milligram			
OMEGA 3 [FISH OIL]	Concomitant						
OMEPRAZOLE	Concomitant	NOT SPECIFIED		20.0 Milligram	1 every 1 Days		
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
RAMIPRIL	Concomitant	NOT SPECIFIED		5.0 Milligram	1 every 1 Days		
XARELTO	Concomitant	Coated tablet		20.0 Milligram	1 every 1 Days		Anticoagulant therapy

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Aneurysm	v.24.1	
Hypoaesthesia	v.24.1	
Hypokinesia	v.24.1	
Iliac artery occlusion	v.24.1	
Paraparesis	v.24.1	
Sensory loss	v.24.1	
Thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04071806	2	2021-04-27	2021-07-08	MAH	2021432188	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
72 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.24.1	
Drug ineffective	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information

***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04071819	2	2021-04-27	2021-08-19	MAH	2021411295	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
59 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
LUMIGAN NOS	Concomitant	SOLUTION OPHTHALMIC	Intraocular	1.0 Gtt	every 1 Days		Glaucoma
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Disturbance in attention	v.24.1	
Dry mouth	v.24.1	
Dysphagia	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	
Headache	v.24.1	
Hypertension	v.24.1	
Loss of personal independence in daily activities	v.24.1	
Mental impairment	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04071827	0	2021-04-27	2021-04-27	MAH	2021410099	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
31 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.24.1	
Hypertension	v.24.1	
Syncope	v.24.1	
Tachycardia	v.24.1	
Vision blurred	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04071929	0	2021-04-27	2021-04-27	MAH	2021416051	Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
28 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Condition aggravated	v.24.1	1 Days
Disease recurrence	v.24.1	1 Days
Seizure	v.24.1	1 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04071939	0	2021-04-27	2021-04-27	MAH	2021412673	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
66 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Flatulence	v.24.1	
Hypertension	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04072030	0	2021-04-27	2021-04-27	MAH	2021416562	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
33 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Months	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Tinnitus	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04072272	1	2021-04-27	2021-04-30	MAH	2021465286	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
38 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PANTOPRAZOLE	Concomitant	NOT SPECIFIED					Gastric disorder
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
SERTRALINE	Concomitant	Capsules					Depression
TRAZODONE	Concomitant						Sleep disorder

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04072399	1	2021-04-27	2021-05-06	MAH	2021263476	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
81 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood pressure fluctuation	v.24.1	
Feeling abnormal	v.24.1	
Heart rate increased	v.24.1	
Hypotension	v.24.1	
Malaise	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04072425	0	2021-04-27	2021-04-27	MAH	21K-028-3867809-00	Study	Consumer/other non health professional

Serious report?
Serious

Death:	No	**Disability:**	No	**Congenital Anomaly:**	No
Life Threatening:	No	**Hospitalization:**	Yes	**Other Medically Important Conditions:**	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
74 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular				COVID-19 immunisation
HUMIRA	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous	40.0 Milligram	1 every 1 Weeks		Crohn's disease

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bacteraemia	v.24.1	
Dyspnoea	v.24.1	1 Days
Headache	v.24.1	
Pyrexia	v.24.1	1 Days
Tremor	v.24.1	1 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04072797	3	2021-04-27	2021-06-24	MAH	2021431421	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
43 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Eyelid ptosis	v.24.1	1 Months

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04072898	1	2021-04-27	2021-06-08	MAH	2021410560	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
37 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dyspnoea	v.24.1	
Heart rate increased	v.24.1	
Hypersensitivity	v.24.1	
Nausea	v.24.1	
Paraesthesia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04072905	0	2021-04-27	2021-04-27	MAH	2021423234	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Drug ineffective	v.24.1	
Suspected COVID-19	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04072938	0	2021-04-27	2021-04-27	MAH	2021405440	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
69 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ATORVASTATIN CALCIUM	Concomitant	Tablets					Blood cholesterol abnormal
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
VITAMIN D3	Concomitant	Capsules		1000.0 IU (International Unit)	every 1 Days		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood pressure decreased	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.24.1	
Hypersensitivity	v.24.1	
Nausea	v.24.1	
Syncope	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04072956	2	2021-04-27	2021-06-17	MAH	2021411787	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
54 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.24.1	
Chest discomfort	v.24.1	
Headache	v.24.1	
Lacrimation increased	v.24.1	
Malaise	v.24.1	
Oropharyngeal pain	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Periorbital swelling	v.24.1	
Throat irritation	v.24.1	
Throat tightness	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04072968	2	2021-04-27	2021-05-18	MAH	2021406234	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
71 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETYLSALICYLIC ACID	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Transient ischaemic attack	v.24.1	1 Months

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04073565	0	2021-04-27	2021-04-27	MAH	20K-028-3674608-00	Study	Consumer/other non health professional

Serious report?
Serious

Death:	No	**Disability:**	No	**Congenital Anomaly:**	No
Life Threatening:	No	**Hospitalization:**	Yes	**Other Medically Important Conditions:**	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
66 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	
Linked	
Linked	
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular			1.0 Months	COVID-19 immunisation
HUMIRA	Suspect	Solution for injection in pre-filled pen	Subcutaneous		1 every 2 Weeks		Psoriatic arthropathy
HUMIRA	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous	40.0 Milligram	1 every 2 Weeks	4.0 Years	Psoriatic arthropathy

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pain	v.24.1	
Pneumonia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04073841	0	2021-04-27	2021-04-27	MAH	2021411873	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
30 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.24.1	
Vertigo	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04073855	2	2021-04-27	2021-06-10	MAH	2021422950	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
46 Years	Female			Recovered/resolved with sequelae

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04074795	1	2021-04-28	2021-08-02	MAH	2021A347655	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
59 Years	Male	183 Centimeter	84 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Depression
BUPROPION	Concomitant		Oral				Depression
FLOMAX	Concomitant	CAPSULE, SUSTAINED-RELEASE	Oral				Depression

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Sleep disorder	v.24.1	
Tremor	v.24.1	1 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04074982	1	2021-04-28	2021-09-13	MAH	2021A347807	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
59 Years	Male	183 Centimeter	84 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Product used for unknown indication
BUPROPION	Concomitant	Tablets	Oral				Nicotine dependence
FLOMAX	Concomitant	CAPSULE, SUSTAINED-RELEASE	Oral				Depression

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Tremor	v.24.1	1 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04075076	2	2021-04-28	2021-09-13	MAH	2021A330861	Spontaneous	Consumer/other non health professional

Serious report?
Serious

Death:	No	**Disability:**	No	**Congenital Anomaly:**	No
Life Threatening:	No	**Hospitalization:**	No	**Other Medically Important Conditions:**	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
59 Years	Female	163 Centimeter	74 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	
Linked	
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Product used for unknown indication
HUMULOG	Concomitant		Unknown				Diabetes mellitus
INSULIN (HUMAN)/INSULIN ISOPHANE HUMAN BYOSINTHETIC	Concomitant		Unknown				Diabetes mellitus
JARDIANCE	Concomitant		Unknown				Diabetes mellitus

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
LANTUS	Concomitant	SOLUTION SUBCUTANEOUS	Unknown				Diabetes mellitus
METFORMIN HYDROCHLORIDE/SITAGLIPTIN PHOSPHATE MONOHYDRATE	Concomitant		Unknown				Diabetes mellitus

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Epistaxis	v.24.1	3 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04076922	0	2021-04-28	2021-04-28	MAH	CANSL2021062416	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
87 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				Product used for unknown indication
ENBREL	Suspect		Subcutaneous	50.0 Milligram	1 every 1 Weeks		Psoriatic arthropathy

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cardiac failure congestive	v.24.1	
Dementia	v.24.1	
Illness	v.24.1	
Liver disorder	v.24.1	
Pulmonary oedema	v.24.1	
Renal disorder	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Urinary tract infection	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04079422	1	2021-04-28	2021-06-23	MAH	2021442458	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04079794	1	2021-04-28	2021-05-06	MAH	2021416859	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
29 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
SERTRALINE	Concomitant	Capsules	Oral	50.0 Milligram	every 1 Days		Anxiety
VENLAFAXINE	Concomitant		Oral	112.5 Milligram	every 1 Days		Anxiety

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dysmenorrhoea	v.24.1	
Heavy menstrual bleeding	v.24.1	12 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04080166	3	2021-04-28	2021-06-23	MAH	2021447813	Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
44 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaemia	v.24.1	
Cerebral venous sinus thrombosis	v.24.1	-93
Dyspnoea	v.24.1	
Haemoglobin decreased	v.24.1	
Headache	v.24.1	
Heavy menstrual bleeding	v.24.1	
Seizure	v.24.1	-93

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Superior sagittal sinus thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04080606	0	2021-04-28	2021-04-28	MAH	2021404949	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_04066819

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.24.1	
Drug ineffective	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04080732	2	2021-04-28	2021-05-25	MAH	2021438464	Spontaneous	Consumer/other non health professional

Serious report?
Serious

Death:	No	**Disability:**	No	**Congenital Anomaly:**	No
Life Threatening:	No	**Hospitalization:**	Yes	**Other Medically Important Conditions:**	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
88 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ELIQUIS FILM COATED	Concomitant	Tablets		5.0 Milligram	1 every 1 Days		
ERGOCALCIFEROL	Concomitant			1000.0 IU (International Unit)	1 every 1 Days		
IRBESARTAN	Concomitant	Tablets		75.0 Milligram	1 every 1 Days		
METOPROLOL	Concomitant			25.0 Milligram	1 every 1 Days		
MIRTAZAPINE	Concomitant	Tablets		15.0 Milligram	1 every 1 Days		
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Months	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Confusional state	v.24.1	
Dysuria	v.24.1	
Herpes zoster	v.24.1	
Inappropriate schedule of product administration	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04080754	1	2021-04-28	2021-05-11	MAH	2021438481	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
39 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.24.1	-105
Diarrhoea	v.24.1	-105
Fatigue	v.24.1	
Hypotension	v.24.1	-105
Syncope	v.24.1	-105
Vaccination site pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04080768	1	2021-04-28	2021-05-04	MAH	2021465277	Spontaneous	Consumer/other non health professional

Serious report?
Serious

Death:	No	**Disability:**	Yes	**Congenital Anomaly:**	No
Life Threatening:	No	**Hospitalization:**	No	**Other Medically Important Conditions:**	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
81 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	E2B_04107445
Linked	E2B_04106641
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arrhythmia	v.24.1	
Balance disorder	v.24.1	
Dizziness	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fall	v.24.1	
Feeling abnormal	v.24.1	
Hypertension	v.24.1	
Ligament sprain	v.24.1	
Nausea	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04080780	2	2021-04-28	2021-06-17	MAH	2021418057	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
60 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
DIPHTHERIA TOXOID ADSORBED/PERTUSSIS VACCINE ACELLULAR 5-COMPONENT/TETANUS TOXOID	Concomitant		Intramuscular			1.0 Days	Immunisation
MICARDIS	Concomitant	Tablets	Oral				Hypertension
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Thrombosis	v.24.1	-98

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04080808	1	2021-04-28	2021-06-07	MAH	2021422272	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
50 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04080820	1	2021-04-28	2021-06-08	MAH	2021438536	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
64 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BETA-CAROTENE/BIOTIN/CALCIUM/CHROMIUM/COPPER/FOLIC ACID/IODINE/IRON/MAGNESIUM/MANGANESE/MOLYBDENUM/NICOTINIC ACID/PANTOTHENIC ACID/PHOSPHORUS/PYRIDOXINE HYDROCHLORIDE/RIBOFLAVIN/SELENIUM/THIAMINE/VITAMIN A/VITAMIN B12/VITAMIN C/VITAMIN D/VITAMIN E	Concomitant				1 every 1 Days		
CLONAZEPAM	Concomitant	Tablets		1.0 Milligram	every 1 Days		Depression

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
ROSUVASTATIN	Concomitant	NOT SPECIFIED		5.0 Milligram	every 1 Days		Blood cholesterol abnormal
SYNTHROID	Concomitant	NOT SPECIFIED			1 every 1 Days		Thyroid disorder
VITAMIN D3	Concomitant	Capsules		2000.0 IU (International Unit)	every 1 Days		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood pressure increased	v.24.1	4 Days
Condition aggravated	v.24.1	
Diabetes mellitus	v.24.1	1 Months
Dysphonia	v.24.1	
Headache	v.24.1	1 Months
Hypoaesthesia oral	v.24.1	
Nausea	v.24.1	
Paraesthesia oral	v.24.1	
Speech disorder	v.24.1	
Thyroid disorder	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04081915	2	2021-04-29	2021-08-19	MAH	MOD-2021-090467	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
53 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	1.0 Dosage forms			COVID-19 immunisation
LEVOTHYROXINE SODIUM	Concomitant	NOT SPECIFIED		25.0 Milligram	1 every 1 Days		Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Eye pruritus	v.24.1	0 Months
Eye swelling	v.24.1	0 Months
Flushing	v.24.1	0 Months

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypersensitivity	v.24.1	0 Months
Lacrimation increased	v.24.1	0 Months

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04084531	0	2021-04-29	2021-04-29	MAH	2021A330856	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
59 Years	Female	163 Centimeter	74 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Product used for unknown indication
INSULIN (HUMAN)/INSULIN ISOPHANE HUMAN BIOSYNTHETIC	Concomitant						Diabetes mellitus
JANUMET	Concomitant	NOT SPECIFIED					Diabetes mellitus
JARDIANCE	Concomitant						Diabetes mellitus
LANTUS	Concomitant	SOLUTION SUBCUTANEOUS					Diabetes mellitus

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Epistaxis	v.24.1	3 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04084720	0	2021-04-29	2021-04-29	MAH	21K-028-3871596-00	Study	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
50 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular			1.0 Days	COVID-19 immunisation
HUMIRA	Suspect	Solution for injection in pre-filled pen	Subcutaneous	40.0 Milligram	1 every 10 Days		Psoriatic arthropathy
HUMIRA	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous	40.0 Milligram	1 every 2 Weeks	2.0 Years	Psoriatic arthropathy

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain	v.24.1	
Arthralgia	v.24.1	
Back pain	v.24.1	
Diarrhoea	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Drug ineffective	v.24.1	
Psoriasis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04087178	0	2021-04-29	2021-04-29	MAH	2021433138	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
54 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
DILTIAZEM	Concomitant	NOT SPECIFIED		240.0 Milligram	every 1 Days		
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
VENLAFAXINE HYDROCHLORIDE	Concomitant			150.0 Milligram	every 1 Days		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dyspnoea	v.24.1	
Fatigue	v.24.1	
Headache	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hepatic enzyme increased	v.24.1	
Hypersomnia	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Off label use	v.24.1	
Pyrexia	v.24.1	
Splenitis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04087201	1	2021-04-29	2021-06-08	MAH	2021432003	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
69 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total		COVID-19 immunisation
VORTIOXETINE HYDROBROMIDE	Concomitant			5.0 Milligram			Depression, Anxiety
VORTIOXETINE HYDROBROMIDE	Concomitant			5.0 Milligram			Depression, Anxiety

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Diarrhoea	v.24.1	
Fatigue	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.24.1	
Multiple sclerosis relapse	v.24.1	
Neck pain	v.24.1	
Vaccination site pain	v.24.1	
Vaccination site swelling	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04087215	4	2021-04-29	2021-07-01	MAH	2021433190	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
69 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
FOLIC ACID	Concomitant	NOT SPECIFIED					
METHOTREXATE	Concomitant	NOT SPECIFIED	Oral	10.0 Milligram	1 every 1 Weeks		Rheumatoid arthritis
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
TYLENOL	Concomitant	NOT SPECIFIED					
XELJANZ	Concomitant		Oral	5.0 Milligram	2 every 1 Days		Rheumatoid arthritis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	3 Days

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Myalgia	v.24.1	3 Days
Pain	v.24.1	3 Days
Rheumatoid arthritis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04087333	0	2021-04-29	2021-04-29	MAH	2021422064	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
72 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
HYDROCHLOROTHIAZIDE/ OLMESARTAN MEDOXOMIL	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
ROSUVASTATIN	Concomitant	NOT SPECIFIED		5.0 Milligram			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Herpes simplex	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04087360	1	2021-04-29	2021-06-23	MAH	2021433038	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
46 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Months	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Contusion	v.24.1	
Pain of skin	v.24.1	
Skin discolouration	v.24.1	
Thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04087394	0	2021-04-29	2021-04-29	MAH	2021423246	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
52 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
LEVOTHYROXINE	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood glucose decreased	v.24.1	
Hypoaesthesia	v.24.1	
Loss of consciousness	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04087469	2	2021-04-29	2021-06-02	MAH	2021425193	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
79 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AMLODIPINE BESILATE	Concomitant		Oral	5.0 Milligram			Hypertension
CORTEF [HYDROCORTISONE]	Concomitant		Oral				Addison's disease
FLUDROCORTISONE ACETATE	Concomitant		Oral	0.1 Milligram	every 1 Days		Addison's disease
INSULIN ASPART	Concomitant		Subcutaneous	8.0 IU (International Unit)	3 every 1 Days		Type 1 diabetes mellitus
NOVORAPID	Concomitant	SOLUTION SUBCUTANEOUS	Subcutaneous				Diabetes mellitus
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
ROSUVASTATIN CALCIUM	Concomitant		Oral	5.0 Milligram			Blood cholesterol

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
SYNTHROID	Concomitant	NOT SPECIFIED	Oral				Thyroid disorder
TRESIBA	Concomitant		Subcutaneous	26.0 IU (International Unit)	every 1 Days		Type 1 diabetes mellitus

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Back pain	v.24.1	
Herpes zoster	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04087523	2	2021-04-29	2021-07-06	MAH	2021423320	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
69 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bronchitis	v.24.1	
Burning sensation	v.24.1	
Diarrhoea	v.24.1	
Illness	v.24.1	
Insomnia	v.24.1	
Mucosal discolouration	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pain	v.24.1	
Vaccination site pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04087581	1	2021-04-29	2021-05-06	MAH	2021455853	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
57 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
SINGULAIR	Concomitant	NOT SPECIFIED	Oral	10.0 Milligram	1 every 1 Days		Hypersensitivity, Asthma

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abnormal dreams	v.24.1	
Anaphylactic reaction	v.24.1	4 Hours
Cough	v.24.1	
Dizziness	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	
Headache	v.24.1	
Hypoaesthesia	v.24.1	
Paraesthesia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information

***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04087670	1	2021-04-29	2021-05-11	MAH	2021425401	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
40 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Migraine with aura	v.24.1	4755 Minutes

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04093091	5	2021-04-30	2021-07-21	MAH	2021433010	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
23 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ETHINYL ESTRADIOL/FERROUS FUMARATE/NORETHINDRONE ACETATE	Concomitant		Oral		every 1 Days		
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Erythema	v.24.1	-31
Inflammation	v.24.1	-31

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Joint warmth	v.24.1	-31
Musculoskeletal pain	v.24.1	
Venous thrombosis limb	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04093543	0	2021-04-30	2021-04-30	MAH	2021432743	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic shock	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04094049	10	2021-04-30	2021-12-01	MAH	2021TUS012388	Study	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
50 Years	Female		57 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BETAMETHASONE	Concomitant		Unknown				Product used for unknown indication
CANNABIDIOL	Concomitant		Unknown				Product used for unknown indication
CELEBREX	Concomitant	Capsules	Unknown	200.0 Milligram			Product used for unknown indication
COVID-19 VACCINE	Suspect		Unknown				COVID-19 immunisation
HYDROXYCHLOROQUINE SULFATE	Concomitant		Unknown	200.0 Milligram			Product used for unknown indication

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
IMMUNOGLOBULIN (HUMAN)	Suspect	Solution for infusion	Unknown	8.0 Gram	2 every 1 Weeks		Primary immunodeficiency syndrome
IMMUNOGLOBULIN (HUMAN)	Suspect	Solution for infusion	Unknown	8.0 Gram	1 every 1 Weeks	8.0 Months	Primary immunodeficiency syndrome
IMMUNOGLOBULIN (HUMAN)	Suspect	Solution for infusion	Unknown	8.0 Gram	1 every 1 Weeks		Primary immunodeficiency syndrome
IMMUNOGLOBULIN (HUMAN)	Suspect	Solution for infusion	Unknown	16.0 Gram	2 every 1 Weeks		Primary immunodeficiency syndrome
IMMUNOGLOBULIN (HUMAN)	Suspect	Solution for infusion	Unknown	1.0 Gram			Primary immunodeficiency syndrome
IMMUNOGLOBULIN (HUMAN)	Suspect	Solution for infusion	Subcutaneous	8.0 Gram	1 every 1 Weeks		Primary immunodeficiency syndrome
IMMUNOGLOBULIN (HUMAN)	Suspect	Solution for infusion	Subcutaneous	16.0 Gram	1 every 1 Weeks		Primary immunodeficiency syndrome
IMMUNOGLOBULIN (HUMAN)	Suspect	Solution for infusion	Unknown				Primary immunodeficiency syndrome
IMMUNOGLOBULIN (HUMAN)	Suspect	Solution for infusion	Unknown	2.0 Gram	2 every 1 Weeks		Primary immunodeficiency syndrome
IMMUNOGLOBULIN (HUMAN)	Suspect	Solution for infusion	Subcutaneous	8.0 Gram	1 every 1 Weeks		Primary immunodeficiency syndrome
IMMUNOGLOBULIN (HUMAN)	Suspect	Solution for infusion	Unknown	6.0 Gram	2 every 1 Weeks		Primary immunodeficiency syndrome
IMMUNOGLOBULIN (HUMAN)	Suspect	Solution for infusion	Unknown	2.0 Gram			Primary immunodeficiency syndrome
IMMUNOGLOBULIN (HUMAN)	Suspect		Subcutaneous	8.0 Gram	1 every 1 Weeks		Primary immunodeficiency syndrome
IMMUNOGLOBULIN (HUMAN)	Suspect	Solution for infusion	Unknown	8.0 Gram	1 every 1 Weeks	274.0 Days	Primary immunodeficiency syndrome

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
IMMUNOGLOBULIN (HUMAN)	Suspect	Solution for infusion	Subcutaneous	8.0 Gram	1 every 1 Weeks		Primary immunodeficiency syndrome
IMMUNOGLOBULIN (HUMAN)	Suspect	Solution for infusion	Unknown	4.0 Gram	2 every 1 Weeks		Primary immunodeficiency syndrome
IMMUNOGLOBULIN (HUMAN)	Suspect	Solution for infusion	Subcutaneous	8.0 Gram	1 every 1 Weeks		Primary immunodeficiency syndrome
TECTA	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication
TRAMACET	Concomitant	Tablets	Unknown				Product used for unknown indication
VENTOLINE [SALBUTAMOL]	Concomitant		Unknown				Product used for unknown indication
VIDEXTRA	Concomitant	Tablets	Unknown	10000.0 IU (International Unit)			Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19 immunisation	v.24.1	
Chest discomfort	v.24.1	
Condition aggravated	v.24.1	
Drug interaction	v.24.1	
Facial operation	v.24.1	
Headache	v.24.1	
Hypersensitivity	v.24.1	
Infusion site erythema	v.24.1	
Infusion site mass	v.24.1	
Infusion site pruritus	v.24.1	
Lip pruritus	v.24.1	
Lip swelling	v.24.1	
Migraine	v.24.1	
Paraesthesia oral	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Peripheral swelling	v.24.1	
Rash	v.24.1	
Swollen tongue	v.24.1	
Tongue pruritus	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04094891	1	2021-04-30	2021-05-11	MAH	2021433017	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic shock	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04094912	1	2021-04-30	2021-05-05	MAH	2021443992	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Months	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.24.1	
Drug ineffective	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 12:58:30 AM
Initial Received Date:	2021-01-01 to 2021-04-30
Latest Received Date:	N/A
Total Number of Reports:	637 Report(s)

Report Information

***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04095016	1	2021-04-30	2021-05-03	MAH	2021BI01004196	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
FAMPYRA	Suspect	TABLET (EXTENDED-RELEASE)	Unknown	10.0 Milligram	2 every 1 Days		Multiple sclerosis
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown				COVID-19 prophylaxis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Therapeutic product effect decreased	v.24.1	
Vaccination complication	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 12:58:30 AM
Initial Received Date: 2021-01-01 to 2021-04-30
Latest Received Date: N/A
Total Number of Reports: 637 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04095783	1	2021-04-30	2021-09-08	MAH	2021A330933	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
62 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Back pain	v.24.1	
Blister	v.24.1	
Pigmentation disorder	v.24.1	
Rash	v.24.1	

Health Canada Santé Canada

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Brand Name/Active Ingredient: covid
Search Date Criteria: 2021-05-01 to 2021-06-15
Reaction Term(s): All/Tous
Serious report?: Both
Type of Report: All
Source of Report: All
Gender: All
Report Outcome: All
Age: All

CAVEAT: This summary is based on information from adverse reaction reports submitted by health professionals and laypersons either directly to Health Canada or via market authorization holders. Each report represents the suspicion, opinion or observation of the individual reporter. The Canada Vigilance Program is a spontaneous reporting system that is suitable to detect signals of potential health product safety issues during the post-market period. The data has been collected primarily by a spontaneous surveillance system in which adverse reactions to health products are reported on a voluntary basis. Under reporting of adverse reactions is seen with both voluntary and mandatory spontaneous surveillance systems. Accumulated case reports should not be used as a basis for determining the incidence of a reaction or estimating risk for a particular product as neither the total number of reactions occurring, nor the number of patients exposed to the health product is known. Because of the multiple factors that influence reporting, quantitative comparisons of health product safety cannot be made from the data. Some of these factors include the length of time a drug is marketed, the market share, size and sophistication of the sales force, publicity about an adverse reaction and regulatory actions. In some cases, the reported clinical data is incomplete and there is not certainty that these health products caused the reported reactions. A given reaction may be due to an underlying disease process or to another coincidental factor. This information is provided with the understanding that the data will be appropriately referenced and used in conjunction with this caveat statement.

Canada

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000948395	0	2021-05-01	2021-05-01	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
49 Years	Female			Recovered/resolved with sequelae

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.24.1	
Fatigue	v.24.1	
Headache	v.24.1	
Hypoaesthesia	v.24.1	
Injection site pain	v.24.1	
Nausea	v.24.1	
Pyrexia	v.24.1	1 Days

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Restlessness	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000948399	0	2021-05-02	2021-05-02	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Ageusia	v.24.1	
Dysgeusia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information

***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000948402	0	2021-05-01	2021-05-01	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
32 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Tenderness	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000948410	0	2021-05-01	2021-05-01	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
42 Years	Female		68 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Heavy menstrual bleeding	v.24.1	
Heavy menstrual bleeding	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000948424	0	2021-05-01	2021-05-01	Hospital		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
52 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular		Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Rash erythematous	v.24.1	
Rash pruritic	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000948427	0	2021-05-01	2021-05-01	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
52 Years		175 Centimeter	85 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR			Once		Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Deafness	v.24.1	
Headache	v.24.1	
Tinnitus	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000948428	0	2021-05-01	2021-05-01	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
42 Years	Female	62 Inch	110 Pound	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular		Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Menstrual disorder	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000948429	0	2021-05-02	2021-05-02	Hospital		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
67 Years	Female		65 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Swelling	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000948430	2	2021-05-02	2021-10-26	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
51 Years				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR			Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	
Injection site pain	v.24.1	
Pain	v.24.1	
Tinnitus	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000948529	0	2021-05-02	2021-05-02	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
48 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	5.0 ml			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
C-reactive protein increased	v.24.1	
Chest pain	v.24.1	
Musculoskeletal pain	v.24.1	
Troponin increased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000948541	0	2021-05-03	2021-05-03	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Visual impairment	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000948544	0	2021-05-03	2021-05-03	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Injection site rash	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000948548	0	2021-05-03	2021-05-03	Community		Spontaneous	Other health professional

Serious report?	Death: No	Disability:	Congenital Anomaly:
Not Serious	Life Threatening:	Hospitalization:	Other Medically Important Conditions:

Patient Information

Age	Gender	Height	Weight	Report Outcome
66 Years	Female	64 Inch	90 Pound	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Injection site rash	v.24.1	
Rash pruritic	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000948561	0	2021-05-03	2021-05-03	Hospital		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
80 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Palliative care	v.24.1	
Ruptured cerebral aneurysm	v.24.1	
Subarachnoid haemorrhage	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000948563	0	2021-05-03	2021-05-03	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect				Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Illness	v.24.1	
Suspected COVID-19	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000948564	0	2021-05-03	2021-05-03	Hospital		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
67 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR			Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cerebral infarction	v.24.1	
Cervical vertebral fracture	v.24.1	
Coma scale abnormal	v.24.1	
Decerebrate posture	v.24.1	
Depressed level of consciousness	v.24.1	
Failure to thrive	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Intracranial aneurysm	v.24.1	
Respiratory distress	v.24.1	
Vascular injury	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
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Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000948566	0	2021-05-03	2021-05-03	Hospital		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
60 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR			Once		Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cerebral haemorrhage	v.24.1	
Cerebral mass effect	v.24.1	
Craniotomy	v.24.1	
Dural arteriovenous fistula	v.24.1	
Hydrocephalus	v.24.1	
Intraventricular haemorrhage	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Ventricular drainage	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

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Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000948567	0	2021-05-03	2021-05-03	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect				Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Erythema	v.24.1	
Feeling hot	v.24.1	
Injection site erythema	v.24.1	
Injection site warmth	v.24.1	
Pain in extremity	v.24.1	
Paraesthesia	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pruritus	v.24.1	
Swelling	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

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Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000948731	0	2021-05-04	2021-05-04	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Erythema	v.24.1	
Pain in extremity	v.24.1	
Skin warm	v.24.1	
Swelling	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000948790	0	2021-05-04	2021-05-04	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
59 Years	Female	168 Centimeter	147 Pound	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular		Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Myalgia	v.24.1	
Periarthritis	v.24.1	

Canada Vigilance
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Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000948792	1	2021-05-04	2021-06-03	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
55 Years	Female	61 Inch	120 Pound	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR		0.5 ml	Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blindness	v.24.1	
Chills	v.24.1	4 Days
Fatigue	v.24.1	
Headache	v.24.1	
Pain	v.24.1	
Pyrexia	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Vision blurred	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000948796	0	2021-05-04	2021-05-04	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
63 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AMLODIPINE	Concomitant	Tablets					
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular		Once		COVID-19 immunisation
CANDESARTAN	Concomitant						
FENOFIBRATE	Concomitant	NOT SPECIFIED					
GLICLAZIDE	Concomitant	Tablets					
HYDROCHLOROTHIAZIDE	Concomitant	Tablets					
METFORMIN	Concomitant	Tablets					
SKYRIZI PREFILLED SYRINGE	Concomitant	SOLUTION SUBCUTANEOUS					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Constipation	v.24.1	
Dizziness	v.24.1	
Feeding disorder	v.24.1	
Nausea	v.24.1	
Pain in extremity	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000948797	2	2021-05-04	2021-06-04	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
45 Years		69 Inch	185 Pound	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR			Once		
BUPROPION XL	Concomitant	TABLET (EXTENDED-RELEASE)	Unknown				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Back pain	v.24.1	
Chest pain	v.24.1	
Chills	v.24.1	
Discomfort	v.24.1	
Headache	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Inflammation	v.24.1	
Pyrexia	v.24.1	1 Days
Spinal pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000948802	0	2021-05-04	2021-05-04	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
63 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular		Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	14 Days
Injection site bruising	v.24.1	14 Days
Pyrexia	v.24.1	14 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000948803	0	2021-05-04	2021-05-04	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
41 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR			Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bell's palsy	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000948804	0	2021-05-04	2021-05-04	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
50 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	1.0 Dosage forms	Once		COVID-19 prophylaxis
IRON	Concomitant	NOT SPECIFIED					
MYRBETRIQ	Concomitant	TABLET (EXTENDED-RELEASE)					
VITAMIN B12	Concomitant	NOT SPECIFIED					
VITAMINS	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.24.1	
Herpes zoster	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Lethargy	v.24.1	
Myalgia	v.24.1	
Pain	v.24.1	
Pain in extremity	v.24.1	
Pyrexia	v.24.1	
Rash	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000948806	0	2021-05-04	2021-05-04	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
48 Years	Male	177 Centimeter	67 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETAMINOPHEN	Concomitant	NOT SPECIFIED					
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.5 ml	Once		COVID-19 immunisation
FINASTERIDE	Concomitant	Tablets					
OMEGA - 3	Concomitant	NOT SPECIFIED					
PANTOPRAZOLE	Concomitant	TABLET (DELAYED-RELEASE)					
VITAMIN D	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Blood creatinine decreased	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cerebellar atrophy	v.24.1	
Chills	v.24.1	
Dizziness	v.24.1	
Fatigue	v.24.1	
Haemoglobin decreased	v.24.1	
Head injury	v.24.1	
Headache	v.24.1	
Hypovolaemia	v.24.1	
Malaise	v.24.1	
Myalgia	v.24.1	
Pain in extremity	v.24.1	
Presyncope	v.24.1	
Pyrexia	v.24.1	
Sinus bradycardia	v.24.1	
Syncope	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000948968	0	2021-05-05	2021-05-05	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
45 Years	Female		135 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE	Suspect						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.24.1	
Pain	v.24.1	
Pyrexia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000948970	0	2021-05-05	2021-05-05	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
44 Years	Female	71 Inch	250 Pound	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
FLUOXETINE	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR			Once		
WELLBUTRIN	Concomitant	TABLET (EXTENDED-RELEASE)					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal discomfort	v.24.1	
Dyspepsia	v.24.1	
Epigastric discomfort	v.24.1	
Eructation	v.24.1	
Flatulence	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Nausea	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000948972	0	2021-05-05	2021-05-05	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
20 Years	Female	62 Inch	140 Pound	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	0.5 ml	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Diarrhoea	v.24.1	
Urticaria	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000948973	0	2021-05-05	2021-05-05	Hospital		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Subcutaneous				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Thrombophlebitis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000948974	0	2021-05-05	2021-05-05	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
59 Years	Male	180 Centimeter	81 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intravenous (not otherwise specified)		Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.24.1	
Dyspnoea	v.24.1	
Headache	v.24.1	
Urticaria	v.24.1	
Vision blurred	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000948975	2	2021-05-05	2021-05-11	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
35 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect				Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Erythema	v.24.1	
Pain	v.24.1	
Pruritus	v.24.1	
Skin warm	v.24.1	
Swelling	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000948998	0	2021-05-06	2021-05-06	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Injection site pain	v.24.1	
Injection site swelling	v.24.1	
Rash	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000949131	0	2021-05-06	2021-05-06	Hospital		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
60 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Seizure	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000949134	0	2021-05-06	2021-05-06	Hospital		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
56 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dyspnoea exertional	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000949138	0	2021-05-06	2021-05-06	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
62 Years	Female	160 Centimeter	48 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Paraesthesia	v.24.1	
Paraesthesia oral	v.24.1	
Pruritus	v.24.1	
Swelling	v.24.1	
Tenderness	v.24.1	
Throat irritation	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000949151	0	2021-05-06	2021-05-06	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
29 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.5 ml	Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.24.1	
Discomfort	v.24.1	
Pain in extremity	v.24.1	
Paraesthesia	v.24.1	
Vertigo	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000949152	0	2021-05-06	2021-05-06	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
45 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Rash	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000949153	0	2021-05-06	2021-05-06	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
43 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.5 ml	Once		COVID-19 immunisation
LORATADINE	Concomitant	NOT SPECIFIED	Unknown				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypersensitivity	v.24.1	1 Days
Paraesthesia	v.24.1	1 Days
Swelling face	v.24.1	1 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000949154	1	2021-05-06	2021-05-16	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
48 Years	Female	59 Inch		Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CONTRACEPTIVES	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Ear pain	v.24.1	
Tinnitus	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000949158	0	2021-05-06	2021-05-06	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
55 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.5 ml	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Tinnitus	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000949360	0	2021-05-07	2021-05-07	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
28 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	30.0 Microgram	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthma	v.24.1	24 Days
Lymphadenopathy	v.24.1	24 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000949364	0	2021-05-07	2021-05-07	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
51 Years	Male	180 Centimeter	108 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	000980588

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
GLICLAZIDE	Concomitant	Tablets					
INVOKANA	Concomitant	Tablets					
OZEMPIC	Concomitant	SOLUTION SUBCUTANEOUS					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Subcutaneous				COVID-19 immunisation
ROSUVASTATIN	Concomitant	NOT SPECIFIED	Subcutaneous				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthritis	v.24.1	
Condition aggravated	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000949365	0	2021-05-07	2021-05-07	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular		Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fall	v.24.1	
Head injury	v.24.1	
Pyrexia	v.24.1	
Skin laceration	v.24.1	
Suture insertion	v.24.1	
Syncope	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000949366	0	2021-05-07	2021-05-07	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
57 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthma	v.24.1	
Condition aggravated	v.24.1	
Headache	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000949367	0	2021-05-08	2021-05-08	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
62 Years	Male	71 Inch	174 Pound	Recovered/resolved with sequelae

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Balance disorder	v.24.1	
Dizziness	v.24.1	
Ear discomfort	v.24.1	
Fatigue	v.24.1	
Headache	v.24.1	
Photosensitivity reaction	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Sensory disturbance	v.24.1	
Tinnitus	v.24.1	
Vision blurred	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000949369	0	2021-05-09	2021-05-09	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
50 Years	Male	165 Centimeter	70 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Palpitations	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000949371	0	2021-05-08	2021-05-08	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR			Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Deafness	v.24.1	
Dizziness	v.24.1	
Pruritus	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000949375	0	2021-05-07	2021-05-07	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
58 Years	Female	60 Inch	140 Pound	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CBD OIL	Concomitant						
DULOXETINE	Concomitant	NOT SPECIFIED	Unknown				
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	1.0 Dosage forms	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.24.1	
Dyspnoea	v.24.1	
Dyspnoea exertional	v.24.1	
Fatigue	v.24.1	
Headache	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Heart rate increased	v.24.1	
Loss of personal independence in daily activities	v.24.1	
Neck pain	v.24.1	
Pain in extremity	v.24.1	
Skin haemorrhage	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000949376	0	2021-05-08	2021-05-08	Community		Spontaneous	Other health professional

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
52 Years	Female	165 Centimeter	59 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASACOL	Concomitant	TABLET (ENTERIC-COATED)					
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.5 ml	Once		COVID-19 immunisation
DUAVIVE	Concomitant	TABLET (IMMEDIATE AND EXTENDED RELEASE)					
HUMIRA (ADALIMUMAB)	Concomitant	NOT SPECIFIED	Unknown				
IMOVANE	Concomitant	Tablets					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cough	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	
Headache	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000949378	0	2021-05-07	2021-05-07	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
41 Years	Female	66 Inch	185 Pound	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	0.5 ml	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Balance disorder	v.24.1	
Condition aggravated	v.24.1	
Dizziness	v.24.1	
Feeling cold	v.24.1	
Peripheral swelling	v.24.1	
Skin discolouration	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000949380	0	2021-05-07	2021-05-07	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
43 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	0.5 ml			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Lymphadenopathy	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000949383	0	2021-05-08	2021-05-08	Community		Spontaneous	Pharmacist

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
33 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypoaesthesia	v.24.1	
Paraesthesia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000949394	0	2021-05-07	2021-05-07	Hospital		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
62 Years	Male	178 Centimeter	66 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BENADRYL	Concomitant	NOT SPECIFIED					
BUSCOPAN	Concomitant	NOT SPECIFIED					
CHAMPIX	Concomitant	Tablets					
CODEINE PHOSPHATE	Concomitant	NOT SPECIFIED	Unknown				
DECADRON	Concomitant	NOT SPECIFIED					
FLUOROURACIL INJECTION USP	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	4320.0 Milligram			
FLUOROURACIL INJECTION USP	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	720.0 Milligram			
IMODIUM	Concomitant	NOT SPECIFIED					
LEUCOVORIN	Suspect	NOT SPECIFIED	Intravenous (not otherwise specified)	720.0 Milligram			

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
LEVOTHYROXINE	Concomitant	NOT SPECIFIED					
MAGIC MOUTHWASH (NYSTATIN)	Concomitant	Tablets					
MAXERAN-10 (10MG TABLET)	Concomitant	Tablets					
OXALIPLATIN	Suspect		Intravenous (not otherwise specified)	150.0 Milligram			
PANTOLOC	Concomitant	TABLET (ENTERIC-COATED)					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					
TRASTUZUMAB	Suspect		Intravenous (not otherwise specified)	265.0 Milligram			
ZOFRAN	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Enterocolitis	v.24.1	
Neutropenia	v.24.1	
Septic shock	v.24.1	
Transfusion	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000949517	0	2021-05-10	2021-05-10	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
49 Years	Female	166 Centimeter	62 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.5 ml			COVID-19 immunisation
IRON	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Feeling cold	v.24.1	
Personality change	v.24.1	
Sensory disturbance	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000949521	0	2021-05-10	2021-05-10	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
73 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.5 ml			COVID-19 immunisation
ESCITALOPRAM	Concomitant	Tablets					
INDAPAMIDE/PERINDOPRIL	Concomitant	NOT SPECIFIED					
ROSUVASTATIN	Concomitant	NOT SPECIFIED	Subcutaneous				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Myalgia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information

***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000949532	0	2021-05-10	2021-05-10	Community		Spontaneous	Pharmacist

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
48 Years	Female	68 Inch	190 Pound	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular		Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Paraesthesia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000949535	0	2021-05-10	2021-05-10	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR			Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Herpes zoster	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000949543	1	2021-05-10	2021-06-12	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
49 Years	Female	65 Inch		Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Herpes zoster	v.24.1	
Polymenorrhoea	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000949544	0	2021-05-10	2021-05-10	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
64 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASPIRIN 81MG	Concomitant	TABLET (ENTERIC-COATED)					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	30.0 Microgram	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Ocular hyperaemia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000949674	0	2021-05-11	2021-05-11	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
45 Years	Female	66 Inch	121 Pound	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.5 ml	Once		COVID-19 immunisation
PANTOLOC	Concomitant	TABLET (ENTERIC-COATED)					
SYNTHROID	Concomitant	NOT SPECIFIED					
VITAMIN D	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000949678	0	2021-05-11	2021-05-11	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
68 Years	Male		198 Pound	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		COVID-19 prophylaxis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pruritus	v.24.1	
Rash maculo-papular	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000949684	0	2021-05-11	2021-05-11	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
33 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CLOBETASOL PROPIONATE	Concomitant	NOT SPECIFIED					
DUPIXENT PRE-FILLED PEN. SINGLE-USE	Concomitant	SOLUTION SUBCUTANEOUS					
FLUOROMETHOLONE OPHTHALMIC	Concomitant	SUSPENSION OPHTHALMIC					
OLOPATADINE	Concomitant	NOT SPECIFIED					
PANTOLOC	Concomitant	TABLET (ENTERIC-COATED)					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR			Once		COVID-19 immunisation
PROTOPIC	Concomitant	OINTMENT TOPICAL					
SYMBICORT	Concomitant	Powder	Inhalation				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Skin exfoliation	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000949686	0	2021-05-12	2021-05-12	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
57 Years	Male		201 Pound	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_04161662

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASPIRIN	Concomitant	NOT SPECIFIED					
ATIVAN	Concomitant	NOT SPECIFIED					
BENZYDAMINE	Concomitant	SOLUTION BUCCAL					
CICLESONIDE	Concomitant	NOT SPECIFIED					
DIGOXIN	Concomitant	NOT SPECIFIED					
ELIQUIS	Concomitant	Tablets					
FUROSEMIDE	Concomitant	NOT SPECIFIED	Unknown				
LIPITOR	Concomitant	NOT SPECIFIED	Unknown				
MONTELUKAST	Concomitant	NOT SPECIFIED					
MYLAN-NITRO SUBLINGUAL SPRAY	Concomitant	METERED-DOSE (AEROSOL)					

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Once		COVID-19 immunisation
SYMBICORT 200/6	Concomitant	NOT SPECIFIED	Unknown				
TEVA-BISOPROLOL	Concomitant	Tablets					
VENTOLIN	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain upper	v.24.1	
Arrhythmia	v.24.1	
Asthma	v.24.1	
Balance disorder	v.24.1	
Chest pain	v.24.1	
Chills	v.24.1	
Choking sensation	v.24.1	
Delirium	v.24.1	
Dizziness	v.24.1	
Dysgeusia	v.24.1	
Dysphagia	v.24.1	
Dyspnoea	v.24.1	
Ear discomfort	v.24.1	
Eye pain	v.24.1	
Fatigue	v.24.1	
Feeling abnormal	v.24.1	
Feeling cold	v.24.1	
Feeling hot	v.24.1	
Heart rate increased	v.24.1	
Hiccups	v.24.1	
Hyperhidrosis	v.24.1	
Hypersensitivity	v.24.1	
Hyperventilation	v.24.1	
Hypoacusis	v.24.1	
Injection site pain	v.24.1	
Malaise	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Mental fatigue	v.24.1	
Muscle tightness	v.24.1	
Nasal congestion	v.24.1	
Ocular discomfort	v.24.1	
Pain	v.24.1	
Pain in extremity	v.24.1	
Panic attack	v.24.1	
Pharyngeal paraesthesia	v.24.1	
Pharyngeal swelling	v.24.1	
Pyrexia	v.24.1	
Rhinorrhoea	v.24.1	
Screaming	v.24.1	
Sensory loss	v.24.1	
Throat irritation	v.24.1	
Tinnitus	v.24.1	
Toothache	v.24.1	
Tremor	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000949688	0	2021-05-11	2021-05-11	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
61 Years		162 Centimeter	99 Pound	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
GLICLAZIDE	Concomitant	Tablets					
LISINOPRIL	Concomitant	Tablets					
METFORMIN	Concomitant	Tablets					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bell's palsy	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000949694	0	2021-05-11	2021-05-11	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:		Disability:		Congenital Anomaly:	
Not Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
68 Years	Female			Recovering/resolving

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				
THYROID THERAPY	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Erythema	v.24.1	
Eye pruritus	v.24.1	
Lip swelling	v.24.1	
Pharyngeal swelling	v.24.1	
Pruritus	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pulmonary congestion	v.24.1	
Throat irritation	v.24.1	
Urticaria	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000949695	0	2021-05-11	2021-05-11	Hospital		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
74 Years	Female	152 Centimeter	74 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Subcutaneous				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.24.1	
Headache	v.24.1	
Hypoaesthesia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000949696	0	2021-05-11	2021-05-11	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
46 Years	Male	72 Inch		Recovering/resolving

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Confusional state	v.24.1	
Disorientation	v.24.1	
Dizziness	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000949697	0	2021-05-11	2021-05-11	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
39 Years	Female	62 Inch		Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Muscle twitching	v.24.1	
Paraesthesia oral	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000949699	0	2021-05-11	2021-05-11	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
79 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	30.0 Microgram			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain	v.24.1	
Duodenogastric reflux	v.24.1	
Eructation	v.24.1	
Nausea	v.24.1	
Pain in extremity	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000949763	2	2021-05-12	2021-05-13	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	Yes	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
55 Years	Female			Fatal

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE	Suspect		Intramuscular		Once		Prophylaxis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain	v.24.1	
Abnormal behaviour	v.24.1	
Anxiety	v.24.1	
Aphasia	v.24.1	
Cerebral thrombosis	v.24.1	
Discoloured vomit	v.24.1	
Electric shock sensation	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.24.1	
Malaise	v.24.1	
Neurological symptom	v.24.1	
Pain	v.24.1	
Platelet count decreased	v.24.1	
Pulmonary embolism	v.24.1	
Pulmonary infarction	v.24.1	
Speech disorder	v.24.1	
Thrombosis	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000949838	0	2021-05-12	2021-05-12	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
66 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	0.5 ml	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Contusion	v.24.1	
Injection site swelling	v.24.1	
Pain	v.24.1	
Rash	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000949842	0	2021-05-12	2021-05-12	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
52 Years	Female	168 Centimeter	75 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		COVID-19 immunisation
ZOMIG	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Heavy menstrual bleeding	v.24.1	
Postmenopausal haemorrhage	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000949843	0	2021-05-13	2021-05-13	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
44 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Subcutaneous				COVID-19 immunisation
EFFEXOR	Concomitant	CAPSULE, EXTENDED RELEASE					
ROBAXACET	Concomitant	NOT SPECIFIED					
TRAZODONE	Concomitant	Tablets					
TRINTELLIX	Concomitant	NOT SPECIFIED					
TYLENOL	Concomitant	Tablets					
ZOLPIDEM	Concomitant	TABLET (ORALLY DISINTEGRATING)					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Burning sensation	v.24.1	
Injection site bruising	v.24.1	
Injection site joint swelling	v.24.1	
Injection site warmth	v.24.1	
Pruritus	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000949845	0	2021-05-12	2021-05-12	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
57 Years	Male	67 Inch	239 Pound	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.5 ml	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blindness transient	v.24.1	
Transient ischaemic attack	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000949846	0	2021-05-12	2021-05-12	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
28 Years	Female	64 Centimeter	110 Pound	Recovering/resolving

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Heavy menstrual bleeding	v.24.1	2 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000949847	0	2021-05-12	2021-05-12	Hospital		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
18 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR		0.3 ml	Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypoaesthesia	v.24.1	
Jaw disorder	v.24.1	
Myalgia	v.24.1	
Vaccination site warmth	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000949852	0	2021-05-12	2021-05-12	Community		Spontaneous	Pharmacist

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
47 Years	Female	67 Inch	240 Pound	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular				COVID-19 immunisation
GLICLAZIDE	Concomitant	Tablets					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypersensitivity	v.24.1	
Rash erythematous	v.24.1	
Rash papular	v.24.1	
Rash pruritic	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000949854	0	2021-05-12	2021-05-12	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Muscle spasms	v.24.1	
Postmenopausal haemorrhage	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000949856	1	2021-05-12	2021-05-19	Hospital		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
35 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	0.5 ml	Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Febrile convulsion	v.24.1	
Pyrexia	v.24.1	
Vaccination complication	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000949859	0	2021-05-12	2021-05-12	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
55 Years	Female		154 Pound	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ADVIL	Concomitant	NOT SPECIFIED					
ANTIPRURITICS (ANTIHISTAMINES, ANESTHETICS, ETC)	Concomitant	NOT SPECIFIED					
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Erythema	v.24.1	7 Days
Feeling hot	v.24.1	7 Days

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pain	v.24.1	7 Days
Swelling	v.24.1	7 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000949864	0	2021-05-12	2021-05-12	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
70 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	0.5 ml	Once		Prophylaxis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Rash	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000949865	0	2021-05-12	2021-05-12	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
51 Years	Female	63 Inch	130 Pound	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CALCIUM & VITAMIN D3	Concomitant	NOT SPECIFIED					
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	0.5 ml	Once		COVID-19 immunisation
LUPIN-ESTRADIOL	Concomitant	Tablets					
MCAL D400	Concomitant	Tablet					
PROMETRIUM	Concomitant	Capsules					
REACTINE	Concomitant	Tablets					
SYNTHROID	Concomitant	NOT SPECIFIED					
TYLENOL ARTHRITIS	Concomitant	TABLET (EXTENDED-RELEASE)					
VITAMIN B12	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain upper	v.24.1	
Fatigue	v.24.1	
Oropharyngeal pain	v.24.1	
Pruritus	v.24.1	
Urticaria	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000949991	0	2021-05-13	2021-05-13	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
31 Years	Male	75 Inch	248 Pound	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Tinnitus	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000949993	0	2021-05-13	2021-05-13	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
47 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.5 ml	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.24.1	
Contusion	v.24.1	
Fatigue	v.24.1	
Paraesthesia	v.24.1	
Pyrexia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000949994	0	2021-05-13	2021-05-13	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
44 Years	Female		190 Pound	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CONTRACEPTIVES	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Subcutaneous		Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Vaginal haemorrhage	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000949996	0	2021-05-13	2021-05-13	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
58 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ANTI-HYPERTENSIVE MEDICATION(S)	Concomitant	NOT SPECIFIED					
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular		Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.24.1	
Dyspnoea	v.24.1	
Loss of personal independence in daily activities	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000950000	0	2021-05-13	2021-05-13	Community		Spontaneous	Other health professional

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
59 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.5 ml	Once		COVID-19 immunisation
DEXILANT	Concomitant	CAPSULE, DELAYED RELEASE					
PARIET, ENTERIC-COATED TABLET 20MG	Concomitant	TABLET (ENTERIC-COATED)					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Sleep disorder	v.24.1	
Tinnitus	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000950002	1	2021-05-13	2021-05-31	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
61 Years	Male	168 Centimeter	78 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASA	Concomitant	NOT SPECIFIED	Unknown				
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular				COVID-19 immunisation
REACTINE	Concomitant	NOT SPECIFIED					
VOLTAREN SR	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.24.1	
Macular oedema	v.24.1	
Myalgia	v.24.1	
Mydriasis	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Palpitations	v.24.1	
Photophobia	v.24.1	
Retinal oedema	v.24.1	
Retinal vein occlusion	v.24.1	
Vision blurred	v.24.1	
Visual field defect	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000950004	1	2021-05-13	2021-06-08	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
61 Years	Female	165 Centimeter	58 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.5 ml	Once		Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bone pain	v.24.1	
Chills	v.24.1	
Diarrhoea	v.24.1	
Dizziness	v.24.1	
Fall	v.24.1	
Fatigue	v.24.1	
Headache	v.24.1	
Lymphadenopathy	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Paraesthesia	v.24.1	
Pyrexia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000950009	0	2021-05-13	2021-05-13	Hospital		Spontaneous	Pharmacist

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
36 Years	Female		87 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AZATHIOPRINE	Concomitant	Tablets					
HYDROXYCHLOROQUINE	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Once		COVID-19 immunisation
PREDNISONE	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Platelet count decreased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000950013	0	2021-05-13	2021-05-13	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
42 Years	Female	169 Centimeter	70 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR					COVID-19 immunisation
CIPRALEX	Concomitant	Tablets					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Sacroiliitis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000950160	0	2021-05-15	2021-05-15	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
55 Years	Female	168 Centimeter	57 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CIPROFLOXACIN	Concomitant	NOT SPECIFIED					
METRONIDAZOLE	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					
VITAMIN D	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Asthenia	v.24.1	
Burning sensation	v.24.1	
Decreased appetite	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Diarrhoea	v.24.1	
Feeling abnormal	v.24.1	
Feeling cold	v.24.1	
Hypoaesthesia	v.24.1	
Liver disorder	v.24.1	
Liver scan abnormal	v.24.1	
Migraine	v.24.1	
Nausea	v.24.1	
Pain	v.24.1	
Paraesthesia	v.24.1	
Tremor	v.24.1	
Vision blurred	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000950161	0	2021-05-16	2021-05-16	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
42 Years	Female	175 Centimeter	89 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.24.1	
Headache	v.24.1	
Lymphadenopathy	v.24.1	
Pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000950162	0	2021-05-16	2021-05-16	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
43 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dyspareunia	v.24.1	
Fatigue	v.24.1	
Menstrual disorder	v.24.1	
Vaginal haemorrhage	v.24.1	
Vaginal infection	v.24.1	
Vulvovaginal burning sensation	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000950163	0	2021-05-16	2021-05-16	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
31 Years	Female	178 Centimeter	75 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Condition aggravated	v.24.1	
Hypoaesthesia	v.24.1	
Lip swelling	v.24.1	
Pain	v.24.1	
Paraesthesia	v.24.1	
Paraesthesia oral	v.24.1	
Rosacea	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000950167	0	2021-05-16	2021-05-16	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
67 Years	Male		77 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Subcutaneous		Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pulmonary embolism	v.24.1	
SARS-CoV-2 test positive	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000950170	0	2021-05-14	2021-05-14	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
62 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.5 ml	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Epistaxis	v.24.1	2 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000950172	0	2021-05-14	2021-05-14	Hospital		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
46 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect				Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood pressure increased	v.24.1	
Flushing	v.24.1	
Heart rate increased	v.24.1	
Injection site pruritus	v.24.1	
Pruritus	v.24.1	
Tongue pruritus	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000950366	0	2021-05-17	2021-05-17	Hospital		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
60 Years	Female			Recovered/resolved with sequelae

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AMLODIPINE	Concomitant	Tablets	Unknown				
DIMENHYDRINATE	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		COVID-19 immunisation
TYLENOL	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood bilirubin increased	v.24.1	
Contusion	v.24.1	7 Days
Gingival bleeding	v.24.1	7 Days
Immune thrombocytopenia	v.24.1	7 Days
Petechiae	v.24.1	7 Days

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Platelet count decreased	v.24.1	7 Days
Reticulocytosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000950367	0	2021-05-17	2021-05-17	MAH		Spontaneous	Consumer/other non health professional

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR			Once		COVID-19 prophylaxis
ELIGARD 22.5MG	Suspect	POWDER FOR SUSPENSION, SUSTAINED-RELEASE	Subcutaneous	22.5 Milligram	1 every 3 Months		Prostate cancer
ELIGARD 22.5MG	Suspect	POWDER FOR SUSPENSION, SUSTAINED-RELEASE	Subcutaneous	22.5 Milligram	1 every 3 Months		Prostate cancer
ELIGARD 22.5MG	Suspect	POWDER FOR SUSPENSION, SUSTAINED-RELEASE	Subcutaneous	22.5 Milligram	1 every 3 Months		Prostate cancer

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Confusional state	v.24.1	
Fatigue	v.24.1	
Gait disturbance	v.24.1	
Gastric dilatation	v.24.1	
General physical health deterioration	v.24.1	
Oedema peripheral	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000950371	0	2021-05-17	2021-05-17	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
71 Years				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ALLOPURINOL	Concomitant	Tablets					
LEVOTHYROXINE	Concomitant	NOT SPECIFIED					
LOSEC	Concomitant	NOT SPECIFIED					
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular				COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Deafness neurosensory	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000950372	0	2021-05-17	2021-05-17	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
23 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Menstruation delayed	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000950374	0	2021-05-17	2021-05-17	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
33 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Erythema	v.24.1	
Nail discolouration	v.24.1	
Pain in extremity	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000950377	0	2021-05-17	2021-05-17	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
47 Years	Female	176 Centimeter	59 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Heavy menstrual bleeding	v.24.1	9 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000950378	0	2021-05-17	2021-05-17	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
35 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Chills	v.24.1	
Fatigue	v.24.1	
Headache	v.24.1	
Injection site pain	v.24.1	
Penile pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000950379	0	2021-05-17	2021-05-17	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
66 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Insomnia	v.24.1	
Loss of personal independence in daily activities	v.24.1	
Neuralgia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000950382	0	2021-05-17	2021-05-17	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
34 Years	Female	66 Inch	138 Pound	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bedridden	v.24.1	10 Days
Chills	v.24.1	10 Days
Dizziness	v.24.1	10 Days
Fatigue	v.24.1	10 Days
Headache	v.24.1	10 Days
Loss of personal independence in daily activities	v.24.1	10 Days
Menstruation irregular	v.24.1	3 Days

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Myalgia	v.24.1	10 Days
Pain in extremity	v.24.1	10 Days
Polymenorrhoea	v.24.1	6 Days
Pyrexia	v.24.1	10 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000950383	0	2021-05-17	2021-05-17	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
41 Years	Female	62 Inch	185 Pound	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ADRENAL-PRO	Concomitant	Capsule					
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR		0.5 ml	Once		COVID-19 immunisation
MAGNESIUM 200	Concomitant	Capsule					
PEAK PERFORMANCE BONE & JOINT PACK WOMEN'S (VITALITY MULTIVITAMIN & MINERAL COMPONENT)	Concomitant	KIT					
THYROID TAB 60MG	Concomitant	Tablets					
THYROID-PRO FORMULA	Concomitant	Capsule					
Thyroid Antibody complex	Concomitant						

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
VITAMIN C	Concomitant	NOT SPECIFIED					
VITAMIN D (1000 IU)	Concomitant	Tablet					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dysmenorrhoea	v.24.1	
Intermenstrual bleeding	v.24.1	13 Days
Thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000950385	0	2021-05-17	2021-05-17	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
71 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASA	Concomitant	NOT SPECIFIED	Unknown				
EFFEXOR	Concomitant	CAPSULE, EXTENDED RELEASE					
LORAZEPAM	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				
RANITIDINE	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	1 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000950386	0	2021-05-17	2021-05-17	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
63 Years	Female		56 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR			Once		COVID-19 immunisation
ESTRADOT 50	Concomitant	PATCH					
PROMETRIUM	Concomitant	Capsules					
SPIRONOLACTONE	Concomitant	Tablets					
VAGIFEM	Concomitant	Vaginal suppository					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000950388	0	2021-05-17	2021-05-17	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
43 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Dizziness	v.24.1	
Hyperhidrosis	v.24.1	
Muscle twitching	v.24.1	
Pallor	v.24.1	
Paraesthesia	v.24.1	
Syncope	v.24.1	
Thirst	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Unresponsive to stimuli	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000950607	0	2021-05-18	2021-05-18	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
76 Years	Female	60 Inch	58 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Deep vein thrombosis	v.24.1	
Erythema	v.24.1	
Mass	v.24.1	
Oedema peripheral	v.24.1	
Swelling	v.24.1	
Tenderness	v.24.1	
Tendonitis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000950608	1	2021-05-18	2021-07-14	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
81 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Capillary leak syndrome	v.24.1	
Erythema	v.24.1	
Musculoskeletal discomfort	v.24.1	
Scab	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000950611	0	2021-05-18	2021-05-18	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
61 Years	Female	66 Inch	110 Pound	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR		0.3 ml	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dysaesthesia	v.24.1	
Neck pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000950614	0	2021-05-18	2021-05-18	Hospital		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
52 Years	Female	62 Inch	190 Pound	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	0.5 ml	Once		COVID-19

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.24.1	
Cough	v.24.1	
Pain	v.24.1	
Pruritus	v.24.1	
Pyrexia	v.24.1	
Swelling face	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Urticaria	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000950615	0	2021-05-18	2021-05-18	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
64 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Deafness neurosensory	v.24.1	
Sudden hearing loss	v.24.1	
Tinnitus	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000950617	0	2021-05-18	2021-05-18	Community		Spontaneous	Physician

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
40 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect				Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Injection site cellulitis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000950618	0	2021-05-18	2021-05-18	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
52 Years	Female	155 Centimeter	65 Kilogram	Recovering/resolving

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				COVID-19

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Vertigo	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000950621	0	2021-05-18	2021-05-18	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
55 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.24.1	
Deafness unilateral	v.24.1	
Loss of personal independence in daily activities	v.24.1	
Pyrexia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000950627	0	2021-05-18	2021-05-18	Community		Spontaneous	Physician

Serious report?	Death:		Disability:	Yes	Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	

Patient Information

Age	Gender	Height	Weight	Report Outcome
40 Years	Male		87 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETAMINOPHEN	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Neuropathy peripheral	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000950628	0	2021-05-18	2021-05-18	Community		Spontaneous	Physician

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
63 Years	Female	170 Centimeter	69 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR			Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Condition aggravated	v.24.1	
Vitiligo	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000950779	0	2021-05-19	2021-05-19	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
40 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	0.5 ml			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Erythema	v.24.1	
Eye movement disorder	v.24.1	
Hyperhidrosis	v.24.1	
Loss of consciousness	v.24.1	
Seizure	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000950790	0	2021-05-19	2021-05-19	Hospital		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
48 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
NOVORAPID FLEXTOUCH - PREFILLED MULTIDOSE DISPOSABLE INSULIN DELIVERY DEVICE CONTAINING A 3ML CARTRIDGE	Concomitant	SOLUTION SUBCUTANEOUS					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				Immunisation
TOUJEO	Concomitant	NOT SPECIFIED	Subcutaneous				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood glucose increased	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cough	v.24.1	
Pharyngeal paraesthesia	v.24.1	
Swelling face	v.24.1	
Swollen tongue	v.24.1	
Wheezing	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000950826	0	2021-05-19	2021-05-19	Hospital		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
51 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dyspnoea	v.24.1	
Oropharyngeal discomfort	v.24.1	
Swelling	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000950828	0	2021-05-19	2021-05-19	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR			Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal discomfort	v.24.1	
Hypophagia	v.24.1	
Nausea	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000950830	1	2021-05-19	2021-06-09	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
44 Years	Female	64 Inch	71 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cerebral venous sinus thrombosis	v.24.1	
Headache	v.24.1	
Seizure	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000950833	0	2021-05-19	2021-05-19	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
45 Years	Female		68 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.5 ml	Once		COVID-19 immunisation
PMS-FERROUS SULFATE	Concomitant	NOT SPECIFIED					
PRO-AAS EC - 80	Concomitant	TABLET (DELAYED-RELEASE)					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Injection site pain	v.24.1	
Muscular weakness	v.24.1	
Myalgia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000950971	0	2021-05-20	2021-05-20	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Illness	v.24.1	
Intensive care	v.24.1	
Mechanical ventilation	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000950974	0	2021-05-20	2021-05-20	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
75 Years	Female	167 Centimeter	81 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AMLODIPINE	Concomitant	Tablets	Unknown				
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect						
HCTZ	Concomitant	NOT SPECIFIED	Unknown				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain	v.24.1	
Fatigue	v.24.1	
Frequent bowel movements	v.24.1	
Myalgia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000950990	0	2021-05-20	2021-05-20	Hospital		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
79 Years	Female		78 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AMLODIPINE	Concomitant	Tablets	Unknown				
ASPIRIN 81MG	Concomitant	TABLET (ENTERIC-COATED)					
CETIRIZINE	Concomitant	Tablets					
CLOPIDOGREL	Concomitant	Tablets					
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect				Once		COVID-19 immunisation
FAMOTIDINE	Concomitant	NOT SPECIFIED					
GLICLAZIDE	Concomitant	Tablets					
IRBESARTAN	Concomitant	Tablets	Unknown				
MAGNESIUM	Concomitant	NOT SPECIFIED					
METFORMIN	Concomitant	Tablets					

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PEG 3350	Concomitant	POWDER FOR SOLUTION ORAL					
PREGABALIN	Concomitant	Capsules					
VENLAFAXINE XR	Concomitant	CAPSULE, EXTENDED RELEASE					
VITAMIN B12	Concomitant	Tablets					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Acute kidney injury	v.24.1	
Acute myocardial infarction	v.24.1	
Condition aggravated	v.24.1	
Diabetes mellitus	v.24.1	
Dyspnoea at rest	v.24.1	
Escherichia urinary tract infection	v.24.1	
General physical health deterioration	v.24.1	
Hypovolaemia	v.24.1	
Pulmonary embolism	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000950991	0	2021-05-20	2021-05-20	Hospital		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
82 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AMITRIPTYLINE	Concomitant	Tablets					
ATENOLOL TABLETS, BP	Concomitant	Tablets					
CITALOPRAM	Concomitant						
DOXYCYCLINE	Concomitant	NOT SPECIFIED					
FERROUS SULFATE	Concomitant	NOT SPECIFIED					
FOLIC ACID	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once	21.0 Days	COVID-19 immunisation
RABEPRAZOLE	Concomitant	NOT SPECIFIED					
VITAMIN B12	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Thrombocytopenia	v.24.1	27 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000950993	0	2021-05-20	2021-05-20	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
51 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.5 ml	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pain in extremity	v.24.1	
Sleep disorder	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000950994	0	2021-05-20	2021-05-20	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
30 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	0.5 ml	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Chills	v.24.1	
Fatigue	v.24.1	
Hypoaesthesia	v.24.1	
Influenza like illness	v.24.1	
Malaise	v.24.1	
Myalgia	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Photosensitivity reaction	v.24.1	
Vaccination site erythema	v.24.1	
Vaccination site inflammation	v.24.1	
Vaccination site pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000950995	0	2021-05-20	2021-05-20	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
42 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR					COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Paraesthesia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000950996	0	2021-05-20	2021-05-20	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
38 Years	Female	160 Centimeter	61 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Parenteral				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Lip swelling	v.24.1	
Vaccination site rash	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000951000	0	2021-05-20	2021-05-20	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
61 Years	Male	178 Centimeter	103 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASPIRIN 81MG	Concomitant	TABLET (ENTERIC-COATED)					
DILTIAZEM CD	Concomitant	CAPSULE, EXTENDED RELEASE					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Erythema	v.24.1	
Inflammation	v.24.1	
Inflammatory pain	v.24.1	
Pollakiuria	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000951004	0	2021-05-20	2021-05-20	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bell's palsy	v.24.1	
Chest pain	v.24.1	
Dyspnoea	v.24.1	
Pyrexia	v.24.1	
Vaccination site erythema	v.24.1	
Vaccination site pain	v.24.1	
Vaccination site swelling	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000951007	0	2021-05-20	2021-05-20	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
66 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect				Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Incorrect dose administered	v.24.1	
Injection site pain	v.24.1	
Wrong technique in product usage process	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000951168	0	2021-05-22	2021-05-22	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
49 Years	Female		135 Pound	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect						Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Injection site pain	v.24.1	
Injection site pruritus	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000951170	0	2021-05-24	2021-05-24	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
50 Years	Female	163 Centimeter	162 Pound	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CELEXA	Concomitant	Tablets					
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular				
OLMESARTAN	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	
Feeling abnormal	v.24.1	
Headache	v.24.1	
Hypotension	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Injection site pain	v.24.1	
Motion sickness	v.24.1	
Movement disorder	v.24.1	
Nausea	v.24.1	
Polymenorrhoea	v.24.1	
Taste disorder	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000951186	0	2021-05-21	2021-05-21	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect						COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Head discomfort	v.24.1	
Headache	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000951188	0	2021-05-21	2021-05-21	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
43 Years	Male	175 Centimeter	93 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR			Once	25.0 Days	
SYMBICORT	Concomitant	Powder	Inhalation				
VENTOLIN	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest discomfort	v.24.1	
Dyspnoea	v.24.1	
Dyspnoea exertional	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000951189	0	2021-05-24	2021-05-24	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
58 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	0.5 ml	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Erythema	v.24.1	
Inflammation	v.24.1	
Injection site mass	v.24.1	
Paraesthesia	v.24.1	
Skin warm	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000951190	0	2021-05-21	2021-05-21	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
34 Years	Female	167 Centimeter	175 Pound	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blister	v.24.1	
Herpes zoster	v.24.1	
Skin burning sensation	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000951192	0	2021-05-22	2021-05-22	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
68 Years	Male	67 Inch	170 Pound	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR			Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain upper	v.24.1	
Arthralgia	v.24.1	
Chest pain	v.24.1	
Chills	v.24.1	
Headache	v.24.1	
Injection site swelling	v.24.1	
Loss of personal independence in daily activities	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Myalgia	v.24.1	
Pain in extremity	v.24.1	
Pyrexia	v.24.1	
Vertigo	v.24.1	
Walking aid user	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000951195	0	2021-05-22	2021-05-22	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect				Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain upper	v.24.1	
Malaise	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000951196	0	2021-05-23	2021-05-23	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
58 Years	Female	64 Inch	118 Pound	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.5 ml	Once		COVID-19 immunisation
SYNTHROID	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Burning sensation	v.24.1	
Fatigue	v.24.1	
Muscular weakness	v.24.1	
Musculoskeletal stiffness	v.24.1	
Paraesthesia	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Paraesthesia oral	v.24.1	
Visual impairment	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000951199	0	2021-05-22	2021-05-22	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
28 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Herpes zoster	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000951200	0	2021-05-23	2021-05-23	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
27 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Once		COVID-19 prophylaxis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pruritus	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000951203	0	2021-05-21	2021-05-21	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
67 Years	Female		74 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CIPROFLOXACIN	Concomitant	NOT SPECIFIED					
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect						COVID-19 immunisation
NABILONE	Concomitant	NOT SPECIFIED					
OXYCODONE	Concomitant	NOT SPECIFIED					
OXYNEO	Concomitant	TABLET (EXTENDED-RELEASE)					
PANTOPRAZOLE	Concomitant	POWDER FOR SOLUTION INTRAVENOUS					
POLYETHYLENE GLYCOL	Concomitant	NOT SPECIFIED					
SULFONAMIDES	Concomitant	NOT SPECIFIED					
SYSTANE	Concomitant	NOT SPECIFIED					

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ZYPREXA	Concomitant	Tablets					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Rash erythematous	v.24.1	
Rash papular	v.24.1	
Rash pruritic	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000951210	0	2021-05-22	2021-05-22	Hospital		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
34 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypoaesthesia	v.24.1	
Paraesthesia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000951344	0	2021-05-25	2021-05-25	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
39 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		COVID-19 immunisation
SYNTHROID	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Lacrimation increased	v.24.1	
Ocular hyperaemia	v.24.1	
Vision blurred	v.24.1	
Visual impairment	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000951345	0	2021-05-25	2021-05-25	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
62 Years	Female	159 Centimeter	160 Pound	Recovering/resolving

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bell's palsy	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000951350	0	2021-05-25	2021-05-25	Community		Spontaneous	Nurse

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
34 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR			Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anti-neutrophil cytoplasmic antibody positive vasculitis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000951351	0	2021-05-25	2021-05-25	Community		Spontaneous	Nurse

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
29 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BENADRYL	Concomitant	NOT SPECIFIED					
IBUPROFEN	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	1.0 Dosage forms	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bell's palsy	v.24.1	
Decreased nasolabial fold	v.24.1	
Dermatochalasis	v.24.1	
Drooling	v.24.1	
Ear pain	v.24.1	
Eye movement disorder	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Facial asymmetry	v.24.1	
Facial paralysis	v.24.1	
Lagophthalmos	v.24.1	
Mastication disorder	v.24.1	
Paraesthesia	v.24.1	
Sinusitis	v.24.1	
Skin wrinkling	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000951352	0	2021-05-25	2021-05-25	Community		Spontaneous	Physician

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
29 Years	Female	172 Centimeter	102 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR			Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pulmonary embolism	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000951354	0	2021-05-25	2021-05-25	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
51 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pain in extremity	v.24.1	
Paraesthesia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000951356	0	2021-05-25	2021-05-25	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR			Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Arthritis	v.24.1	
Bell's palsy	v.24.1	
Facial paralysis	v.24.1	
Headache	v.24.1	
Myalgia	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Osteitis	v.24.1	
Pain in jaw	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000951453	1	2021-05-25	2021-06-01	Hospital		Spontaneous	Physician

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
48 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dysphagia	v.24.1	
Pharyngeal swelling	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000951523	0	2021-05-26	2021-05-26	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.24.1	
Dyspnoea	v.24.1	
Fatigue	v.24.1	
Fibromyalgia	v.24.1	
Hot flush	v.24.1	
Migraine	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000951524	0	2021-05-26	2021-05-26	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
43 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml			COVID-19 prophylaxis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Rash	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000951529	0	2021-05-26	2021-05-26	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
63 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ATACAND	Concomitant	Tablets					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				COVID-19 prophylaxis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blister	v.24.1	
Erythema	v.24.1	
Feeling hot	v.24.1	
Flushing	v.24.1	
Nausea	v.24.1	
Photophobia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000951530	0	2021-05-26	2021-05-26	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
24 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml			Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Nausea	v.24.1	1 Days
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000951531	0	2021-05-26	2021-05-26	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
69 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ATACAND	Concomitant	Tablets					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		COVID-19 immunisation
SINGULAIR	Concomitant	NOT SPECIFIED					
STATINS	Concomitant	NOT SPECIFIED					
WARFARIN	Concomitant	Tablets					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Decreased appetite	v.24.1	
Dyspepsia	v.24.1	
Faeces discoloured	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Gastric haemorrhage	v.24.1	
Heart rate increased	v.24.1	
Melaena	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000951533	0	2021-05-26	2021-05-26	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
52 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dry eye	v.24.1	
Lethargy	v.24.1	
Vision blurred	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000951539	0	2021-05-26	2021-05-26	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
40 Years	Female	66 Inch	220 Pound	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect				Once	49.0 Days	
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Injection site erythema	v.24.1	
Injection site swelling	v.24.1	
Injection site warmth	v.24.1	
Rash	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000951548	0	2021-05-26	2021-05-26	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
51 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR			Once		
CIALIS	Concomitant	Tablets					
DEXEDRINE TABLETS (5MG)	Concomitant	Tablets					
DOXEPIN	Concomitant	Capsules					
LORAZEPAM	Concomitant	Tablets					
SERTRALINE-25	Concomitant	Capsules					
VYVANSE	Concomitant	Capsules					
ZOLPIDEM	Concomitant	TABLET (ORALLY DISINTEGRATING)					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Deafness	v.24.1	
Tinnitus	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000951553	0	2021-05-26	2021-05-26	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
26 Years	Female	63 Inch	145 Pound	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BACLOFEN-10 - TAB	Concomitant	Tablets					
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect				Once		
DIANE-35	Concomitant	Tablets					
EPIPEN 0.3MG	Concomitant	SOLUTION INTRAMUSCULAR					
NASONEX	Concomitant	SPRAY, METERED DOSE					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypoaesthesia	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Muscle spasms	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000951562	0	2021-05-26	2021-05-26	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
27 Years	Female	65 Inch	139 Pound	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
EFFEXOR	Concomitant	CAPSULE, EXTENDED RELEASE					
MELATONIN	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Once		COVID-19
RELAXEN TAB	Concomitant	Tablets					
SUMATRIPTAN	Concomitant	NOT SPECIFIED					
VYVANSE	Concomitant	Capsules					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain upper	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood pressure decreased	v.24.1	
Burning sensation	v.24.1	
Diarrhoea	v.24.1	
Feeling cold	v.24.1	
Hyperhidrosis	v.24.1	
Loss of consciousness	v.24.1	
Nausea	v.24.1	
Pain in extremity	v.24.1	1 Days
Pallor	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000951705	1	2021-05-27	2021-06-11	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
67 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	000951708

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASPIRIN	Concomitant	NOT SPECIFIED					
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR					
ATORVASTATIN	Concomitant	NOT SPECIFIED					
CANDESARTAN	Concomitant						
DILTIAZEM	Concomitant	NOT SPECIFIED					
JAMP-FER	Concomitant	Capsule					
JANUMET	Concomitant	NOT SPECIFIED					
MULTIVITAMINE(S)	Concomitant	NOT SPECIFIED					
PANTOPRAZOLE	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Myalgia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000951708	1	2021-05-27	2021-06-11	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
63 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	000951705

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASPIRIN	Concomitant	NOT SPECIFIED					
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR					
ATORVASTATIN	Concomitant	Tablets					
BISOPROLOL	Concomitant	Tablets					
INSULIN	Concomitant	NOT SPECIFIED					
JANUMET	Concomitant	NOT SPECIFIED	Unknown				
MULTIVITAMINE(S)	Concomitant	NOT SPECIFIED					
PANTOPRAZOLE	Concomitant	NOT SPECIFIED					
VALSARTAN	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000951716	0	2021-05-27	2021-05-27	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
32 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Heavy menstrual bleeding	v.24.1	8 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000951728	0	2021-05-27	2021-05-27	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
83 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Confusional state	v.24.1	
Hypophagia	v.24.1	
Hypotension	v.24.1	
Malaise	v.24.1	1 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000951730	0	2021-05-27	2021-05-27	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
31 Years	Female	152 Centimeter	79 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Localised oedema	v.24.1	
Lymph node pain	v.24.1	
Lymphadenopathy	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000951732	0	2021-05-27	2021-05-27	Hospital		Spontaneous	Pharmacist

Serious report?	Death:	Yes	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
54 Years	Female	160 Centimeter	68 Kilogram	Fatal

Link / Duplicate Report Information

Record Type	Link AER** Number
Duplicate	000977087

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular		Once		COVID-19 prophylaxis
METFORMIN/SITAGLIPTIN E	Concomitant						
TYLENOL	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cerebral haemorrhage	v.24.1	
Cerebral venous thrombosis	v.24.1	5 Days
Cerebrovascular accident	v.24.1	
Coagulopathy	v.24.1	
Decompressive craniectomy	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	
Headache	v.24.1	
Immune thrombocytopenia	v.24.1	
Nausea	v.24.1	
Platelet transfusion	v.24.1	
Thrombectomy	v.24.1	
Venous hypertension	v.24.1	
Vision blurred	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000951733	0	2021-05-27	2021-05-27	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
35 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Loss of consciousness	v.24.1	
Malaise	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000951739	0	2021-05-27	2021-05-27	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
28 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular		Once		COVID-19

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Ecchymosis	v.24.1	
Platelet count decreased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000951740	0	2021-05-27	2021-05-27	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
46 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR			Once		COVID-19 immunisation
VYVANSE	Concomitant	Capsules					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cough	v.24.1	
Diarrhoea	v.24.1	
Fatigue	v.24.1	
Nasal congestion	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000951744	0	2021-05-27	2021-05-27	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR			Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Nausea	v.24.1	
Vertigo	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000951745	0	2021-05-27	2021-05-27	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
40 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Injection site cellulitis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000951755	0	2021-05-27	2021-05-27	Hospital		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
78 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASA	Concomitant	NOT SPECIFIED	Unknown				
CALCIUM & VITAMIN D	Concomitant	NOT SPECIFIED					
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular				COVID-19 immunisation
DECADRON	Concomitant	NOT SPECIFIED					
REVLIMID	Concomitant	Capsules					
SYNTHROID	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cutaneous vasculitis	v.24.1	
Purpura	v.24.1	14 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000951797	0	2021-05-28	2021-05-28	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
45 Years	Female	64 Inch	190 Pound	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.5 ml			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.24.1	
Hypersensitivity	v.24.1	
Musculoskeletal stiffness	v.24.1	
Nausea	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000951902	0	2021-05-28	2021-05-28	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Electromagnetic interference	v.24.1	
Nervousness	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000951903	0	2021-05-28	2021-05-28	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Breast cancer	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000951905	0	2021-05-28	2021-05-28	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect						COVID-19 prophylaxis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Discomfort	v.24.1	
Erythema	v.24.1	
Skin warm	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000951915	0	2021-05-28	2021-05-28	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
53 Years	Male			Recovering/resolving

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Atrial fibrillation	v.24.1	
Pericardial effusion	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000951916	0	2021-05-28	2021-05-28	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
65 Years	Male		110 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETYLSALICYLIC ACID	Concomitant	Tablets	Unknown				
BISOPROLOL	Concomitant	Tablets					
COVERSYL	Concomitant	Tablets					
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	0.5 ml	Once		COVID-19 immunisation
DELATESTRYL	Concomitant	SOLUTION INTRAMUSCULAR					
INDAPAMIDE	Concomitant	Tablets					
SPIRIVA	Concomitant	NOT SPECIFIED	Unknown				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Herpes zoster	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000951918	0	2021-05-28	2021-05-28	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
60 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR					Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood glucose increased	v.24.1	
Diabetes mellitus inadequate control	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000951919	0	2021-05-28	2021-05-28	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
30 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Burning sensation	v.24.1	
Dizziness	v.24.1	
Erythema	v.24.1	
Fatigue	v.24.1	
Flushing	v.24.1	
Pruritus	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000951922	0	2021-05-28	2021-05-28	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
37 Years				Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR			Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Alopecia areata	v.24.1	
Condition aggravated	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000951923	1	2021-05-28	2021-06-15	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
33 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular				COVID-19 immunisation
MULTIVITAMINS WITH MINERALS	Concomitant	NOT SPECIFIED					
TESTOSTERONE	Concomitant						
TRIBULUS TERRESTRIS	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest discomfort	v.24.1	
Chest pain	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.24.1	
Fatigue	v.24.1	
Headache	v.24.1	
Influenza like illness	v.24.1	
Malaise	v.24.1	
Myocarditis	v.24.1	
Pain	v.24.1	
Pyrexia	v.24.1	
Throat tightness	v.24.1	
Troponin increased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000951924	0	2021-05-28	2021-05-28	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
25 Years	Female	152 Centimeter	53 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.24.1	
Erythema	v.24.1	
Pruritus	v.24.1	
Urticaria	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000951927	1	2021-05-29	2021-06-02	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
68 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Once		
SANDOZ PERINDOPRIL ERBUMINE	Concomitant	Tablets					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
C-reactive protein increased	v.24.1	
Loss of personal independence in daily activities	v.24.1	
Myalgia	v.24.1	
Weight increased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000951929	0	2021-05-28	2021-05-28	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
69 Years	Female	167 Centimeter	102 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular				COVID-19 immunisation
HYDROCHLOROTHIAZIDE	Concomitant	Tablets					
RAMIPRIL	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bell's palsy	v.24.1	
Polyarthritis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000951930	0	2021-05-29	2021-05-29	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
43 Years	Female	61 Inch	125 Pound	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ADVIL	Concomitant	NOT SPECIFIED					
ELDERBERRY	Concomitant	LIQUID ORAL					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Once		COVID-19 immunisation
VITAMIN C	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Polymenorrhoea	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000951937	0	2021-05-30	2021-05-30	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
13 Years	Female	160 Centimeter	43 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR			Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.24.1	
Dyspnoea	v.24.1	
Fatigue	v.24.1	
Headache	v.24.1	
Pyrexia	v.24.1	
Suffocation feeling	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000951938	0	2021-05-30	2021-05-30	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
25 Years	Female	163 Centimeter	107 Pound	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml			COVID-19 immunisation
TACTUPUMP	Concomitant	GEL					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Axillary pain	v.24.1	
Chest pain	v.24.1	
Dyspnoea	v.24.1	
Fatigue	v.24.1	
Feeling abnormal	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Lymphadenopathy	v.24.1	
Peripheral swelling	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000952114	0	2021-05-31	2021-05-31	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
55 Years	Male	171 Centimeter	86 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intravenous (not otherwise specified)				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Erectile dysfunction	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000952119	0	2021-05-31	2021-05-31	Community		Spontaneous	Physician

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
37 Years	Female	169 Centimeter	92 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	0.5 ml	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cellulitis	v.24.1	
Injection site erythema	v.24.1	
Injection site induration	v.24.1	
Injection site swelling	v.24.1	
Injection site warmth	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000952121	0	2021-05-31	2021-05-31	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
59 Years	Female	170 Centimeter	85 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
LOSEC CAPSULES 20MG	Concomitant	CAPSULE, DELAYED RELEASE					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR			Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pharyngeal swelling	v.24.1	
Swollen tongue	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000952123	0	2021-05-31	2021-05-31	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
60 Years	Female	163 Centimeter	86 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACT OLAPATADINE 0.2%	Concomitant	SOLUTION OPHTHALMIC					
CALCIUM	Concomitant	NOT SPECIFIED					
COQ10 (SWISS HERBAL)	Concomitant	Capsules					
ESTROGENS	Concomitant	NOT SPECIFIED					
MULTIVITAMINS WITH MINERALS	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				COVID-19 immunisation
PROBIOTIC	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	
Hyperhidrosis	v.24.1	
Nausea	v.24.1	
Vertigo	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000952126	0	2021-05-31	2021-05-31	Hospital		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
85 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR			Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hallucinations, mixed	v.24.1	
Headache	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000952128	0	2021-05-31	2021-05-31	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
47 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Back pain	v.24.1	
Blood pressure fluctuation	v.24.1	
Blood pressure increased	v.24.1	
Chest discomfort	v.24.1	
Deafness	v.24.1	
Diplopia	v.24.1	
Dyschezia	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dysuria	v.24.1	
Ear pain	v.24.1	
Feeling hot	v.24.1	
Head discomfort	v.24.1	
Hypoaesthesia	v.24.1	
Hypoaesthesia oral	v.24.1	
Impaired work ability	v.24.1	
Insomnia	v.24.1	
Lymphadenopathy	v.24.1	
Muscle spasms	v.24.1	
Muscle tightness	v.24.1	
Muscle twitching	v.24.1	
Myalgia	v.24.1	
Paraesthesia oral	v.24.1	
Sensory loss	v.24.1	
Spinal pain	v.24.1	
Swelling face	v.24.1	
Temperature intolerance	v.24.1	
Tinnitus	v.24.1	
Toothache	v.24.1	
Weight decreased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000952129	0	2021-05-31	2021-05-31	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
48 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Erythema	v.24.1	
Hypersensitivity	v.24.1	
Oropharyngeal pain	v.24.1	
Pruritus	v.24.1	
Urticaria	v.24.1	
Vaccination site erythema	v.24.1	
Vaccination site pain	v.24.1	
Vaccination site rash	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Vaccination site swelling	v.24.1	
Vaccination site warmth	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000952130	0	2021-05-31	2021-05-31	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
75 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Asthenia	v.24.1	
Back pain	v.24.1	
Bone pain	v.24.1	
Injected limb mobility decreased	v.24.1	
Injection site inflammation	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Lethargy	v.24.1	
Loss of personal independence in daily activities	v.24.1	
Malaise	v.24.1	
Musculoskeletal pain	v.24.1	
Myalgia	v.24.1	
Pain	v.24.1	
Pain in extremity	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000952131	0	2021-06-01	2021-06-01	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
31 Years	Female	65 Inch		Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	0.5 ml	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Amenorrhoea	v.24.1	
Suppressed lactation	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000952132	0	2021-05-31	2021-05-31	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR			Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.24.1	
Rash erythematous	v.24.1	
Seizure	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000952137	0	2021-05-31	2021-05-31	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
47 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Stevens-Johnson syndrome	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000952138	0	2021-05-31	2021-05-31	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	000952141
Linked	000952144

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypoaesthesia	v.24.1	
Pain	v.24.1	
Paraesthesia	v.24.1	
Sleep disorder	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000952141	0	2021-05-31	2021-05-31	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	000952138

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Vision blurred	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000952144	0	2021-05-31	2021-05-31	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	000952138

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Alopecia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000952325	1	2021-06-01	2021-06-01	Community		Spontaneous	Other health professional

Serious report?	Death:	Yes	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
71 Years	Female			Fatal

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	000952346

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		COVID-19 immunisation
ZOFRAN	Suspect	Tablets	Oral				Nausea

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain	v.24.1	
Asthenia	v.24.1	
Cerebrovascular accident	v.24.1	
Chest pain	v.24.1	
Heart rate increased	v.24.1	
Muscle rigidity	v.24.1	
Muscle spasms	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000952326	0	2021-06-01	2021-06-01	Hospital		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
78 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
KEYTRUDA FOR I.V. INFUSION. 4 ML SINGLE USE VIAL.	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)				
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Subcutaneous				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Autoimmune colitis	v.24.1	
Rectal haemorrhage	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000952327	0	2021-06-01	2021-06-01	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
43 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Condition aggravated	v.24.1	
Fatigue	v.24.1	
Headache	v.24.1	
SAPHO syndrome	v.24.1	
Tenderness	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000952329	0	2021-06-01	2021-06-01	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
44 Years	Female	170 Centimeter	63 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain	v.24.1	
Decreased appetite	v.24.1	
Dizziness	v.24.1	
Fatigue	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000952330	0	2021-06-01	2021-06-01	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
37 Years	Female	65 Inch	210 Pound	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intradermal				COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Polymenorrhoea	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000952333	0	2021-06-01	2021-06-01	Community		Spontaneous	Physician

Serious report?	Death:		Disability:		Congenital Anomaly:	
Not Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
59 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR			Once		
ELTROXIN	Concomitant	Tablets					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.24.1	
Headache	v.24.1	
Macule	v.24.1	
Pyrexia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000952338	0	2021-06-01	2021-06-01	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
30 Years	Female	62 Inch		Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Erythema	v.24.1	
Pruritus	v.24.1	
Skin injury	v.24.1	
Swelling	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000952485	0	2021-06-02	2021-06-02	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
33 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
FLONASE	Concomitant	NOT SPECIFIED	Unknown				
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Once		COVID-19 immunisation
ZYRTEC - TAB 10MG	Concomitant	Tablets					COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Confusional state	v.24.1	
Dyspnoea	v.24.1	
Lymphadenopathy	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Musculoskeletal stiffness	v.24.1	
Pain in extremity	v.24.1	
Palpitations	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000952492	0	2021-06-02	2021-06-02	Community		Spontaneous	Physician

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:	Yes	Other Medically Important Conditions:	

Patient Information

Age	Gender	Height	Weight	Report Outcome
26 Years	Male	180 Centimeter	108 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR			Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Myocarditis	v.24.1	
Troponin I increased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000952493	0	2021-06-02	2021-06-02	Community		Spontaneous	Physician

Serious report?	Death:		Disability:	Yes	Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	

Patient Information

Age	Gender	Height	Weight	Report Outcome
50 Years	Female	162 Centimeter	65 Kilogram	Recovering/resolving

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect				Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Diarrhoea	v.24.1	
Fatigue	v.24.1	
Pyrexia	v.24.1	3 Days
Vaccination site haematoma	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000952502	0	2021-06-02	2021-06-02	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
48 Years	Female			Recovering/resolving

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blister	v.24.1	
Herpes zoster	v.24.1	
Pain	v.24.1	
Rash	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000952636	0	2021-06-03	2021-06-03	Hospital		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
32 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular				
TRI-CYCLEN TABLETS	Concomitant	Tablets					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Injection site erythema	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000952641	0	2021-06-03	2021-06-03	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
55 Years	Male	182 Centimeter	82 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Ankylosing spondylitis	v.24.1	
Arthralgia	v.24.1	
Myalgia	v.24.1	
Swelling	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000952643	0	2021-06-03	2021-06-03	Hospital		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
36 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
APRI 21	Concomitant	Tablets					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Axillary pain	v.24.1	
Breast pain	v.24.1	
Paraesthesia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000952648	0	2021-06-03	2021-06-03	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
77 Years		183 Centimeter	124 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASA	Concomitant	NOT SPECIFIED	Unknown				
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR					
PLAQUENIL	Concomitant	Tablets	Unknown				
RAMIPRIL	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Ageusia	v.24.1	
Anosmia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000952652	0	2021-06-03	2021-06-03	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
68 Years	Female	159 Centimeter	62 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pain in extremity	v.24.1	
Thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000952655	0	2021-06-03	2021-06-03	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
39 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Vaccination site erythema	v.24.1	
Vaccination site pruritus	v.24.1	
Vaccination site warmth	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000952656	0	2021-06-03	2021-06-03	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
39 Years	Male	67 Inch	175 Pound	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Angina pectoris	v.24.1	
Inflammation	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000952657	0	2021-06-03	2021-06-03	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					COVID-19

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Back pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000952658	0	2021-06-03	2021-06-03	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
49 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR		1.0 Dosage forms	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Dizziness	v.24.1	
Fatigue	v.24.1	
Head discomfort	v.24.1	
Headache	v.24.1	
Hypoaesthesia	v.24.1	
Hypotension	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pain in extremity	v.24.1	
Syncope	v.24.1	

Canada Vigilance
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Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000952671	0	2021-06-03	2021-06-03	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
65 Years		182 Centimeter	90 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	0.5 ml	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blue toe syndrome	v.24.1	
Dysgeusia	v.24.1	
Erythema	v.24.1	
Oedema	v.24.1	
Skin burning sensation	v.24.1	

Canada Vigilance
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Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000952673	0	2021-06-03	2021-06-03	Community		Spontaneous	Pharmacist

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
36 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	0.5 ml	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Injection site pain	v.24.1	
Injection site pruritus	v.24.1	
Injection site swelling	v.24.1	
Vaccination site cellulitis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000952674	0	2021-06-03	2021-06-03	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR			Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.24.1	
Dyspnoea	v.24.1	
Pericarditis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000952675	0	2021-06-03	2021-06-03	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:	Yes	Other Medically Important Conditions:	

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect				Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Chest pain	v.24.1	
Insomnia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000952677	0	2021-06-03	2021-06-03	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:		Disability:	Yes	Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR			Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Paralysis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

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Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000952848	0	2021-06-04	2021-06-04	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
34 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CIPRALEX	Concomitant	Tablets					
FREYA 28	Concomitant	Tablets					
LANSOPRAZOLE	Concomitant	CAPSULE, DELAYED RELEASE					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		COVID-19 immunisation
REACTINE	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Lymph node pain	v.24.1	
Lymphadenopathy	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000952850	1	2021-06-04	2021-06-16	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
26 Years	Female	69 Inch	130 Pound	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intravenous (not otherwise specified)	1.0 Dosage forms	Once		COVID-19 prophylaxis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	
Hypoaesthesia	v.24.1	
Muscular weakness	v.24.1	
Pain in extremity	v.24.1	
Paraesthesia	v.24.1	
Pyrexia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

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Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000952854	0	2021-06-04	2021-06-04	Community		Spontaneous	Pharmacist

Serious report?	Death:		Disability:	Yes	Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	

Patient Information

Age	Gender	Height	Weight	Report Outcome
22 Years	Female	170 Centimeter	75 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.24.1	
Myalgia	v.24.1	
Pyrexia	v.24.1	

Canada Vigilance
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Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000952856	0	2021-06-04	2021-06-04	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
77 Years	Female	60 Inch	155 Pound	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular		Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Muscular weakness	v.24.1	
Palpitations	v.24.1	
Presyncope	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

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Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000952857	0	2021-06-05	2021-06-05	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
26 Years	Male		70 Kilogram	Recovering/resolving

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	0.5 ml			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.24.1	5 Days
General symptom	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

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Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000952859	0	2021-06-04	2021-06-04	Community		Spontaneous	Other health professional

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:	Yes	Other Medically Important Conditions:	

Patient Information

Age	Gender	Height	Weight	Report Outcome
38 Years	Male	173 Centimeter	78 Kilogram	Recovering/resolving

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
KETOCONAZOLE	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		COVID-19 immunisation
VITAMIN C	Concomitant	NOT SPECIFIED					
VITAMIN D	Concomitant	NOT SPECIFIED					
ZINC	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Myocarditis	v.24.1	

Canada Vigilance
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Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000952860	0	2021-06-06	2021-06-06	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
31 Years	Female	160 Centimeter		Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Burning sensation	v.24.1	
Discomfort	v.24.1	
Pain	v.24.1	
Rash maculo-papular	v.24.1	

Canada Vigilance
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Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000952861	0	2021-06-06	2021-06-06	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
40 Years	Female	168 Centimeter	59 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CETIRIZINE /00884302/	Concomitant						
FLONASE	Concomitant	NOT SPECIFIED	Unknown				
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Herpes zoster	v.24.1	
Neuralgia	v.24.1	
Rash	v.24.1	

Canada Vigilance
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Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000952869	0	2021-06-05	2021-06-05	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
40 Years	Female	160 Centimeter	62 Kilogram	Recovered/resolved with sequelae

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Head discomfort	v.24.1	
Injection site pain	v.24.1	5 Days
Joint swelling	v.24.1	
Lymphadenopathy	v.24.1	
Menstruation delayed	v.24.1	
Migraine	v.24.1	
Myalgia	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Nausea	v.24.1	
Oropharyngeal pain	v.24.1	
Pain in extremity	v.24.1	
Pyrexia	v.24.1	

Canada Vigilance
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Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000952924	0	2021-06-04	2021-06-04	MAH		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
47 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID VACCINE	Suspect						
ENABLEX	Concomitant	TABLET (EXTENDED-RELEASE)					
ETHANOL	Suspect	NOT SPECIFIED	Oral	3.0 Dosage forms			
TWD INDICA DRIED (INDICA) BY TWEED	Suspect		Inhalation	3.0 Dosage forms	1 every 1 Days		Substance use

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood pressure abnormal	v.24.1	
Contusion	v.24.1	
Dizziness	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fall	v.24.1	
Feeling hot	v.24.1	
Hyperhidrosis	v.24.1	
Nausea	v.24.1	
Syncope	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000953099	1	2021-06-07	2021-06-07	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
39 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Herpes zoster	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

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Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000953100	0	2021-06-07	2021-06-07	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BISOPROLOL	Concomitant	Tablets					
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	0.5 ml	Once		COVID-19 immunisation
VITAMIN D	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Herpes zoster	v.24.1	
Paraesthesia	v.24.1	
Pruritus	v.24.1	
Rash	v.24.1	

Canada Vigilance
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Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000953101	0	2021-06-07	2021-06-07	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
27 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Palpitations	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000953102	0	2021-06-07	2021-06-07	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
43 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Herpes zoster	v.24.1	
Rash pruritic	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000953104	0	2021-06-07	2021-06-07	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
44 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Breast pain	v.24.1	
Pain in extremity	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000953113	0	2021-06-07	2021-06-07	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
65 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	0.5 ml		56.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Lymphadenopathy	v.24.1	50 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000953117	0	2021-06-07	2021-06-07	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
25 Years	Female	70 Inch	175 Pound	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR		0.3 ml			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Face oedema	v.24.1	
Generalised oedema	v.24.1	
Paraesthesia	v.24.1	
Throat tightness	v.24.1	
Urticaria	v.24.1	2 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000953121	0	2021-06-07	2021-06-07	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
59 Years	Female	67 Inch	250 Pound	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID VACCINE	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.5 ml	Once		
RIVAROXABAN	Concomitant	Film-coated tablet	Unknown				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000953124	0	2021-06-07	2021-06-07	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
31 Years	Male	76 Inch	255 Pound	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	0.5 ml			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Rash erythematous	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000953126	0	2021-06-07	2021-06-07	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Herpes virus infection	v.24.1	
Neuralgia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000953129	0	2021-06-07	2021-06-07	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
41 Years	Female	68 Inch	155 Pound	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CONCERTA	Concomitant	TABLET (EXTENDED-RELEASE)					
DULOXETINE HYDROCHLORIDE	Concomitant	CAPSULE, DELAYED RELEASE	Oral				
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Once		COVID-19 immunisation
TRAMADOL HYDROCHLORIDE	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Burning sensation	v.24.1	
Herpes zoster	v.24.1	
Pruritus	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Rash erythematous	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000953133	0	2021-06-07	2021-06-07	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
66 Years				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Product administered at inappropriate site	v.24.1	
Product administration error	v.24.1	
Shoulder injury related to vaccine administration	v.24.1	
Vaccination site movement impairment	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000953136	0	2021-06-07	2021-06-07	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
34 Years	Male	188 Centimeter	125 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular		Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.24.1	
Nausea	v.24.1	
Vertigo positional	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000953137	0	2021-06-07	2021-06-07	Hospital		Spontaneous	Other health professional

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
32 Years	Female			Recovering/resolving

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.24.1	
Nausea	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000953316	0	2021-06-08	2021-06-08	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
21 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ALYSENA 28	Concomitant	Tablets					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Headache	v.24.1	
Intermenstrual bleeding	v.24.1	
Muscle strain	v.24.1	
Musculoskeletal chest pain	v.24.1	
Pulmonary thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000953317	0	2021-06-08	2021-06-08	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
42 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID VACCINE	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	1.0 Dosage forms			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bell's palsy	v.24.1	20 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000953318	0	2021-06-08	2021-06-08	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
48 Years	Female	244 Centimeter	106 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Emotional disorder	v.24.1	
Malaise	v.24.1	
Menstrual disorder	v.24.1	
Menstruation delayed	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000953319	0	2021-06-08	2021-06-08	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
43 Years	Female	160 Centimeter	79 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
OMEGA	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Subcutaneous	1.0 Dosage forms	Once		COVID-19 immunisation
SERTRALINE	Concomitant	Capsules					
VITAMIN D	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dysmenorrhoea	v.24.1	
Loss of personal independence in daily activities	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000953320	0	2021-06-08	2021-06-08	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
31 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.24.1	
Loss of personal independence in daily activities	v.24.1	
Nasopharyngitis	v.24.1	
Pyrexia	v.24.1	
Vaccination site movement impairment	v.24.1	
Vaccination site pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000953322	0	2021-06-08	2021-06-08	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
67 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ARAVA	Concomitant	Tablets					
COVERSYL PLUS	Concomitant	NOT SPECIFIED					
JANUMET	Concomitant	NOT SPECIFIED					
LYRICA	Concomitant	Capsules					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intradermal	1.0 Dosage forms	Once		COVID-19
PREDNISONE	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Haemoglobin decreased	v.24.1	
Monocyte count decreased	v.24.1	
Neutrophil count decreased	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Petechiae	v.24.1	
Platelet count decreased	v.24.1	
Purpura	v.24.1	
White blood cell count decreased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000953325	0	2021-06-08	2021-06-08	Hospital		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
80 Years	Female	62 Inch	140 Pound	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASPIRIN	Concomitant	NOT SPECIFIED					
HYDROCHLOROTHIAZIDE	Concomitant	Tablets					
LIPITOR	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Rheumatoid arthritis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000953330	0	2021-06-08	2021-06-08	Hospital		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
45 Years	Male	174 Centimeter	97 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	0.5 ml	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood creatine phosphokinase increased	v.24.1	
Blood immunoglobulin A decreased	v.24.1	
Blood immunoglobulin M decreased	v.24.1	
Fibrin D dimer increased	v.24.1	
Rash	v.24.1	
Red blood cell sedimentation rate increased	v.24.1	
Skin exfoliation	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000953331	0	2021-06-08	2021-06-08	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
29 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR			Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain upper	v.24.1	
Balance disorder	v.24.1	
Chest pain	v.24.1	
Costochondritis	v.24.1	
Cyanosis	v.24.1	
Discomfort	v.24.1	
Dizziness	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dyspnoea	v.24.1	
Hyperhidrosis	v.24.1	
Loss of consciousness	v.24.1	
Musculoskeletal chest pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000953394	0	2021-05-26	2021-05-26	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
63 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE	Suspect		Intramuscular	0.5 ml	Once		Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abnormal sensation in eye	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000953515	0	2021-06-09	2021-06-09	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
51 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AMLODIPINE	Concomitant	Tablets	Unknown				
METFORMIN	Concomitant	Tablets					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		COVID-19 prophylaxis
SYNTHROID	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bell's palsy	v.24.1	
Dizziness	v.24.1	
Dysgeusia	v.24.1	
External ear pain	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Facial paralysis	v.24.1	
Hypoaesthesia oral	v.24.1	
Muscular weakness	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000953517	0	2021-06-09	2021-06-09	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
48 Years	Female	61 Inch	115 Pound	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID VACCINE	Suspect	SOLUTION INTRAMUSCULAR					COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bell's palsy	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000953525	0	2021-06-09	2021-06-09	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
30 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Dizziness	v.24.1	
Malaise	v.24.1	
Somnolence	v.24.1	
Vertigo	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000953529	0	2021-06-09	2021-06-09	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Breast mass	v.24.1	
Lymphadenopathy	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000953530	0	2021-06-09	2021-06-09	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
52 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dehydration	v.24.1	
Diarrhoea	v.24.1	
Irritable bowel syndrome	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000953532	0	2021-06-09	2021-06-09	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
33 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml			Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Product administered at inappropriate site	v.24.1	
Vaccination site movement impairment	v.24.1	15 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000953535	0	2021-06-09	2021-06-09	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
77 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ALENDRONATE	Concomitant	Tablets					
ATORVASTATIN CALCIUM	Concomitant	Tablets					
DULOXETINE HYDROCHLORIDE	Concomitant	CAPSULE, DELAYED RELEASE					
ELTROXIN	Concomitant	Tablets					
NITROLINGUAL PUMPSPRAY	Concomitant	METERED-DOSE (PUMP)					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		COVID-19 immunisation
SALBUTAMOL	Concomitant	NOT SPECIFIED					

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
TUDORZA GENUAIR 1 INHALER WITH 30 ACTUATIONS & 1 INHALER WITH 60 ACTUATIONS	Concomitant	POWDER, METERED DOSE					
VALSARTAN	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Deafness neurosensory	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000953537	0	2021-06-09	2021-06-09	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
60 Years	Female	64 Inch	168 Pound	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	000953749

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CELEBREX	Concomitant	Capsules					
GLUCOSAMINE SULFATE	Concomitant	Capsules					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml			COVID-19 immunisation
TYLENOL ARTHRITIS	Concomitant	TABLET (EXTENDED-RELEASE)					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.24.1	6 Days
Fatigue	v.24.1	
Paraesthesia oral	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Rash	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000953538	0	2021-06-09	2021-06-09	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Injection site erythema	v.24.1	
Injection site pain	v.24.1	
Injection site rash	v.24.1	
Injection site swelling	v.24.1	
Injection site warmth	v.24.1	
Nausea	v.24.1	
Paraesthesia	v.24.1	
Pruritus	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000953733	0	2021-06-10	2021-06-10	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
29 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bell's palsy	v.24.1	
Headache	v.24.1	
Malaise	v.24.1	
Neck pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000953736	0	2021-06-10	2021-06-10	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
26 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ALESSE 28	Concomitant	Tablets					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Heavy menstrual bleeding	v.24.1	
Muscle spasms	v.24.1	
Pain	v.24.1	
Uterine spasm	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000953737	0	2021-06-10	2021-06-10	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
63 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID VACCINE	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dermatitis allergic	v.24.1	
Urticaria	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000953743	0	2021-06-10	2021-06-10	Community		Spontaneous	Other health professional

Serious report?	Death:		Disability:		Congenital Anomaly:	
Not Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	

Patient Information

Age	Gender	Height	Weight	Report Outcome
12 Years	Female	60 Inch	80 Pound	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR		0.3 ml			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pyrexia	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000953744	0	2021-06-10	2021-06-10	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
58 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular		Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cellulitis	v.24.1	
Incision site erythema	v.24.1	
Incision site rash	v.24.1	
Injection site erythema	v.24.1	
Injection site pain	v.24.1	
Injection site swelling	v.24.1	
Postoperative wound complication	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Rash	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000953749	0	2021-06-09	2021-06-09	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
60 Years	Female	64 Inch	168 Pound	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	000953537

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CELEBREX	Concomitant	Capsules					
GLUCOSAMINE SULFATE	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Once		COVID-19 immunisation
TYLENOL ARTHRITIS PAIN 8H	Concomitant	TABLET (EXTENDED-RELEASE)					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Swollen tongue	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000953950	0	2021-06-07	2021-06-07	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
56 Years	Female	173 Centimeter	127 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				COVID-19

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Urticaria	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000953951	0	2021-06-12	2021-06-12	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
64 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	0.5 ml			COVID-19

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cerebrovascular accident	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000953955	0	2021-06-11	2021-06-11	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
37 Years	Female	170 Centimeter	70 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
LEVOTHYROXINE	Concomitant	NOT SPECIFIED	Unknown				
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.24.1	
Dyspnoea	v.24.1	
Ventricular extrasystoles	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000953958	0	2021-06-11	2021-06-11	Community		Spontaneous	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
62 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ATORVASTATIN	Concomitant	Tablets					
CEPHALEXIN	Concomitant	NOT SPECIFIED					
CLOPIDOGREL	Concomitant	Tablets					
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular				
DEXAMETHASONE	Concomitant	Tablets					
EMEND	Concomitant	Capsules					
LAPELGA SINGLE-USE PREFILLED SYRINGE	Concomitant	SOLUTION SUBCUTANEOUS					
OLANZAPINE	Concomitant	NOT SPECIFIED					
ONDANSETRON	Concomitant	Tablets					
PROCHLORAZINE	Concomitant	Tablets					

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
TAMSULOSIN	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Gout	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000953963	1	2021-06-12	2021-06-17	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
41 Years	Female	156 Centimeter	49 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MULTIPLE VITAMINS	Concomitant	Capsules					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular			40.0 Days	COVID-19 prophylaxis
VITAMIN B COMPLEX	Concomitant						
VITAMIN D	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain	v.24.1	
Bladder irritation	v.24.1	
Chills	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Eye infection	v.24.1	
Eye pain	v.24.1	
Lacrimation increased	v.24.1	
Lymphadenopathy	v.24.1	
Ocular hyperaemia	v.24.1	
Oropharyngeal pain	v.24.1	
Pollakiuria	v.24.1	
Pyrexia	v.24.1	
Rectal haemorrhage	v.24.1	
Stomatitis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000953965	0	2021-06-11	2021-06-11	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
83 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once	28.0 Days	COVID-19 immunisation
RABEPRAZOLE	Concomitant	NOT SPECIFIED					
SYNTHROID	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Blood creatinine increased	v.24.1	
Chills	v.24.1	
Decreased appetite	v.24.1	
Dehydration	v.24.1	
Diarrhoea	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	
Liver function test increased	v.24.1	
Pyrexia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000953966	0	2021-06-11	2021-06-11	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
25 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	0.5 ml	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Skin warm	v.24.1	
Urticaria	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000953967	0	2021-06-11	2021-06-11	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
20 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	0.5 ml			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Skin warm	v.24.1	
Urticaria	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000953968	0	2021-06-11	2021-06-11	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
28 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	0.5 ml	Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Breast pain	v.24.1	
Erythema	v.24.1	
Injection site erythema	v.24.1	
Injection site warmth	v.24.1	
Nipple pain	v.24.1	
Pain in extremity	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information

***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000953969	0	2021-06-11	2021-06-11	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
47 Years	Male	178 Centimeter	76 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID VACCINE	Suspect	SOLUTION INTRAMUSCULAR		0.5 ml			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.24.1	13 Days
Vertigo	v.24.1	13 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000953970	0	2021-06-11	2021-06-11	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
37 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular		Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Axillary pain	v.24.1	
Erythema	v.24.1	
Myalgia	v.24.1	
Skin warm	v.24.1	
Swelling	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000953973	0	2021-06-11	2021-06-11	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Herpes zoster	v.24.1	
Neuralgia	v.24.1	
Pain	v.24.1	
Paraesthesia	v.24.1	
Rash	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000953976	0	2021-06-11	2021-06-11	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Ascites	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000953977	0	2021-06-13	2021-06-13	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID VACCINE	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular		Once		
MAVIK	Concomitant	Capsules					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Blood pressure increased	v.24.1	
Dizziness	v.24.1	
Palpitations	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000953979	0	2021-06-13	2021-06-13	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID VACCINE	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular		Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Erythema	v.24.1	
Feeling hot	v.24.1	
Headache	v.24.1	
Peripheral swelling	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000953981	0	2021-06-12	2021-06-12	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
42 Years	Male	175 Centimeter	65 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Subcutaneous		Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pericardial cyst	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000953987	1	2021-06-13	2021-06-16	Hospital		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
64 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular				COVID-19 immunisation
Statine	Concomitant						
anti-hypertenseur	Concomitant						
anti-plaquettaire	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cerebrovascular accident	v.24.1	
Ischaemic stroke	v.24.1	
Thrombectomy	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000954162	0	2021-06-14	2021-06-14	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
70 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Feeling hot	v.24.1	
Influenza like illness	v.24.1	
Pain in extremity	v.24.1	
Peripheral swelling	v.24.1	
Vaccination site pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000954163	0	2021-06-14	2021-06-14	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
39 Years	Male		83 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal distension	v.24.1	
Anxiety	v.24.1	
Asthenia	v.24.1	
Constipation	v.24.1	
Dyschezia	v.24.1	
Fear of eating	v.24.1	
Feeling abnormal	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Flatulence	v.24.1	
Impaired work ability	v.24.1	
Loss of personal independence in daily activities	v.24.1	
Pain	v.24.1	
Panic reaction	v.24.1	
Suicidal ideation	v.24.1	
Weight decreased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000954164	0	2021-06-14	2021-06-14	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
56 Years	Female		74 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CLONAZEPAM	Concomitant	Tablets					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		COVID-19
XELODA	Concomitant	Tablets					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypoaesthesia	v.24.1	
Hypoaesthesia oral	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000954166	0	2021-06-15	2021-06-15	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
56 Years	Female		60 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID VACCINE	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular		Once		COVID-19

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Burning sensation	v.24.1	
Fatigue	v.24.1	
Hypoaesthesia	v.24.1	
Pain	v.24.1	
Pain in extremity	v.24.1	
Paraesthesia	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pruritus	v.24.1	
Rash	v.24.1	
Sensitive skin	v.24.1	
Skin burning sensation	v.24.1	
Skin warm	v.24.1	
Tremor	v.24.1	
Urticaria	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000954172	0	2021-06-14	2021-06-14	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
70 Years	Female	147 Centimeter	47 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	0.5 ml	Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Erythema	v.24.1	
Feeling hot	v.24.1	
Sensitive skin	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000954174	0	2021-06-14	2021-06-14	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
48 Years	Female	64 Inch	150 Pound	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Once		COVID-19 immunisation
TRANEXAMIC ACID	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Heavy menstrual bleeding	v.24.1	
Menstruation irregular	v.24.1	2 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000954178	0	2021-06-14	2021-06-14	Hospital		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
88 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
IRBESARTAN	Concomitant	Tablets					
LEVODOPA-CARBIDOPA 100-25	Concomitant	Tablets					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Once		
ROSUVASTATIN	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypotension	v.24.1	
Incoherent	v.24.1	
Somnolence	v.24.1	
Unresponsive to stimuli	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000954181	0	2021-06-14	2021-06-14	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
39 Years	Female	163 Centimeter	64 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	1.0 Dosage forms			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
CSF protein increased	v.24.1	
Guillain-Barre syndrome	v.24.1	
Muscular weakness	v.24.1	
Paraesthesia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000954407	0	2021-06-15	2021-06-15	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
46 Years	Female		53 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain upper	v.24.1	
Chest discomfort	v.24.1	
Dizziness	v.24.1	
Dizziness postural	v.24.1	
Fatigue	v.24.1	
Feeling abnormal	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Feeling hot	v.24.1	
Headache	v.24.1	
Heart rate increased	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000954410	0	2021-06-15	2021-06-15	Hospital		Spontaneous	Consumer/other non health professional

Serious report?	Death:	Yes	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
76 Years	Male			Fatal

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR			Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Aphasia	v.24.1	
Cerebrovascular accident	v.24.1	
Endotracheal intubation	v.24.1	
Motor dysfunction	v.24.1	
Thrombectomy	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000954411	0	2021-06-15	2021-06-15	Hospital		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
71 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Deep vein thrombosis	v.24.1	
Pain in extremity	v.24.1	
Pulmonary embolism	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000954412	0	2021-06-15	2021-06-15	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
51 Years	Female	173 Centimeter	86 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ESTRACE	Concomitant	Tablets					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR			Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Condition aggravated	v.24.1	
Fatigue	v.24.1	
Food intolerance	v.24.1	
Mast cell activation syndrome	v.24.1	
Migraine	v.24.1	
Nausea	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000954415	0	2021-06-15	2021-06-15	Hospital		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
63 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID VACCINE	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dyspnoea	v.24.1	
Fatigue	v.24.1	
Headache	v.24.1	
Hypoaesthesia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000954417	0	2021-06-15	2021-06-15	Hospital		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
79 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Acute kidney injury	v.24.1	
Bursitis	v.24.1	
Chest discomfort	v.24.1	
Fatigue	v.24.1	
Myalgia	v.24.1	
Pericarditis	v.24.1	
Peripheral swelling	v.24.1	
Urinary tract infection	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000954418	0	2021-06-15	2021-06-15	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
46 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				Prophylaxis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Amenorrhoea	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000954422	0	2021-06-15	2021-06-15	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
69 Years		157 Centimeter	59 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASPIRIN	Concomitant	NOT SPECIFIED					
ATIVAN	Concomitant	NOT SPECIFIED					
AVAMYS	Concomitant	SPRAY, METERED DOSE					
BLOOD GLUCOSE TEST STRIPS	Concomitant						
CODEINE PHOSPHATE SYRUP	Concomitant	Syrup					
HYDROVAL CREAM 0.2%	Concomitant	Cream					
OMEPRAZOLE	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		
REACTINE	Concomitant	NOT SPECIFIED					
ROSUVASTATIN	Concomitant	NOT SPECIFIED					

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
SALICYLIC ACID	Concomitant	NOT SPECIFIED					
SENOKOT	Concomitant	NOT SPECIFIED					
SYNTHROID	Concomitant	NOT SPECIFIED					
TRELEGY ELLIPTA	Concomitant	Inhalation powder					
TYLENOL EXTRA STRENGTH EZ	Concomitant	Tablets					
VENTOLIN HFA	Concomitant	METERED-DOSE (AEROSOL)					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pruritus	v.24.1	
Rash pruritic	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000954423	0	2021-06-15	2021-06-15	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
39 Years	Female			Recovered/resolved with sequelae

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CITALOPRAM	Concomitant						
CLONAZEPAM	Concomitant	Tablets					
MIRENA	Concomitant	INSERT (EXTENDED-RELEASE)					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		COVID-19 prophylaxis
WELLBUTRIN	Concomitant	TABLET (EXTENDED-RELEASE)					
ZOLPIDEM	Concomitant	TABLET (ORALLY DISINTEGRATING)					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal adhesions	v.24.1	
Abdominal pain	v.24.1	
Condition aggravated	v.24.1	
Dysmenorrhoea	v.24.1	
Endometriosis	v.24.1	
Laparoscopic surgery	v.24.1	
Ovarian cyst	v.24.1	
Postoperative wound infection	v.24.1	
Seroma	v.24.1	
Uterine adhesions	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000954428	0	2021-06-15	2021-06-15	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
69 Years	Female	161 Centimeter	84 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASPIRIN	Concomitant	NOT SPECIFIED					
BETADERM	Concomitant	NOT SPECIFIED					
BLEXTEN	Concomitant	Tablets					
CARBAMAZEPINE	Concomitant	NOT SPECIFIED					
CETIRIZINE	Concomitant	Tablets					
CRESTOR	Concomitant	Tablets					
EPIPEN	Concomitant	SOLUTION INTRAMUSCULAR					
METOPROLOL	Concomitant	Tablets	Unknown				
NORTRIPTYLINE	Concomitant	Capsules					
OMNARIS	Concomitant	SPRAY, METERED DOSE					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once	34.0 Days	

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
RABEPRAZOLE	Concomitant	NOT SPECIFIED					
VITAMIN D	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Rash pruritic	v.24.1	
Urticaria	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000954433	0	2021-06-15	2021-06-15	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dermatitis allergic	v.24.1	
Macule	v.24.1	
Pruritus	v.24.1	
Urticaria	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000954435	0	2021-06-15	2021-06-15	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
45 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID VACCINE	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				
AVAMYS	Concomitant	SPRAY, METERED DOSE					
OLMESARTAN	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Discomfort	v.24.1	
Joint swelling	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000954439	0	2021-06-15	2021-06-15	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
60 Years	Male	67 Inch	162 Pound	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular		Once		COVID-19 immunisation
CRESTOR - 10MG	Concomitant	Tablets					
REACTINE	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Erythema	v.24.1	
Mouth ulceration	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000954445	0	2021-06-15	2021-06-15	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
38 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ATIVAN	Concomitant	NOT SPECIFIED					
IMOVANE	Concomitant	Tablets					
MIRTAZAPINE	Concomitant	Tablets					
NAPROSYN	Concomitant	NOT SPECIFIED					
PANTOLOC	Concomitant	TABLET (ENTERIC-COATED)					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR			Once		
WELLBUTRIN XL	Concomitant	TABLET (EXTENDED-RELEASE)					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Contusion	v.24.1	
Ligament sprain	v.24.1	
Pain in extremity	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000954449	1	2021-06-15	2021-06-24	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
61 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID VACCINE	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular		Once	74.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Deep vein thrombosis	v.24.1	
Dyspnoea	v.24.1	
Fatigue	v.24.1	
Headache	v.24.1	
Pain in extremity	v.24.1	
Peripheral swelling	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000954452	0	2021-06-15	2021-06-15	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR			Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Deep vein thrombosis	v.24.1	
Pain in extremity	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04096674	1	2021-05-01	2021-09-09	MAH	2021A353049	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
63 Years	Female	163 Centimeter	77 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pruritus	v.24.1	
Rash	v.24.1	
Skin haemorrhage	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04097943	1	2021-05-03	2021-09-09	MAH	2021A366968	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
70 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04099401	1	2021-05-03	2021-08-13	MAH	2021A354148	Study	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
713 Months	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Unknown				Product used for unknown indication
FASENRA	Suspect	NOT SPECIFIED	Subcutaneous	30.0 Milligram			Asthma
PREDNISONE	Concomitant	NOT SPECIFIED	Unknown	15.0 Milligram	1 every 1 Days		
SPIRIVA	Concomitant	NOT SPECIFIED	Unknown				
VENTOLIN	Concomitant	NOT SPECIFIED	Unknown				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pulmonary mass	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04100519	1	2021-05-03	2021-05-10	MAH	2021431913	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
75 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ATORVASTATIN	Concomitant		Oral	40.0 Milligram	every 1 Days		Hypercholesterolaemia
MAGNESIUM	Concomitant	NOT SPECIFIED	Oral	300.0 Milligram			Muscle spasms
METFORMIN	Concomitant		Oral	250.0 Milligram	every 1 Days		Glucose tolerance impaired
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.24.1	1 Days
Syncope	v.24.1	1 Days
Vertigo	v.24.1	1 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04101174	0	2021-05-03	2021-05-03	MAH	2021426958	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
47 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AMLODIPINE	Concomitant	Tablets					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
VENLAFAXINE HYDROCHLORIDE	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypoaesthesia	v.24.1	1 Months
Pharyngeal hypoaesthesia	v.24.1	1 Months
Rash erythematous	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Rash pruritic	v.24.1	
Vaccination site hypoaesthesia	v.24.1	1 Months
Vaccination site paraesthesia	v.24.1	1 Months

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04101233	2	2021-05-03	2021-06-10	MAH	2021455524	Spontaneous	Physician

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
73 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
SYNTHROID	Concomitant	NOT SPECIFIED	Oral	0.075 Milligram	1 every 1 Days		Hypothyroidism

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Disturbance in attention	v.24.1	489 Hours
Dizziness	v.24.1	489 Hours
Feeling abnormal	v.24.1	489 Hours
Myalgia	v.24.1	489 Hours
Vertigo	v.24.1	489 Hours

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04101239	1	2021-05-03	2021-05-11	MAH	2021433056	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
59 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
LYRICA	Concomitant	Capsules		50.0 Milligram			Pain, Herpes zoster
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
RAMIPRIL	Suspect	NOT SPECIFIED	Unknown	7.5 Milligram			Hypertension
TYLENOL	Concomitant	NOT SPECIFIED		650.0 Milligram			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Gait disturbance	v.24.1	
Headache	v.24.1	
Hypertension	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Migraine	v.24.1	
Photophobia	v.24.1	915 Minutes
Therapeutic product effect decreased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04101245	2	2021-05-03	2021-07-01	MAH	2021432984	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pruritus	v.24.1	-76
Swelling	v.24.1	-76
Vaccination site erythema	v.24.1	-76

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04101261	1	2021-05-03	2021-05-19	MAH	2021290780	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
92 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ATORVASTATIN	Concomitant			20.0 Milligram			
CILAZAPRIL;HYDROCHLOROTHIAZIDE	Concomitant						
DILTIAZEM	Concomitant			120.0 Milligram			
EDOXABAN	Concomitant			60.0 Milligram			
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
THYROXINE	Concomitant	NOT SPECIFIED		50.0 Microgram			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Rash	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Rash maculo-papular	v.24.1	
Rash papular	v.24.1	
Urticaria	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04101846	2	2021-05-03	2021-06-09	MAH	2021476255	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
25 Years	Female		98 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CYCLOBENZAPRINE HYDROCHLORIDE	Concomitant						
NAPROSYN E	Concomitant	TABLET (ENTERIC-COATED)					
NUVARING	Concomitant	RING (SLOW-RELEASE)	Vaginal			5.0 Years	Contraception
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pulmonary embolism	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04103002	1	2021-05-04	2021-08-30	MAH	CA2021AMR094640	Study	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
73 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_02837352
Linked	
Linked	
Linked	
Linked	E2B_02990989
Linked	E2B_02990989
Linked	
Linked	
Linked	
Linked	
Linked	E2B_02837352

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				COVID-19

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MEPOLIZUMAB	Suspect	Powder for injection	Subcutaneous	100.0 Milligram			Product used for unknown indication, Asthma
MEPOLIZUMAB	Suspect		Subcutaneous	100.0 Milligram			Product used for unknown indication, Asthma

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hospitalisation	v.24.1	
Hypoaesthesia	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Paraesthesia	v.24.1	
Product dose omission issue	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04103774	4	2021-05-04	2021-09-08	MAH	CA2021AMR094615	Study	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
74 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_02700434
Linked	
Linked	E2B_02269098
Linked	E2B_02157007
Linked	E2B_01376292
Linked	
Linked	
Linked	
Linked	E2B_03567130
Linked	
Linked	
Linked	
Linked	
Linked	E2B_03188625
Linked	E2B_03110442
Linked	E2B_02700434
Linked	

Record Type	Link AER** Number
Linked	E2B_02269098
Linked	E2B_02157007
Linked	
Linked	
Linked	
Linked	E2B_03567130
Linked	
Linked	
Linked	
Linked	
Linked	E2B_03188625
Linked	E2B_03110442
Linked	E2B_02700434
Linked	
Linked	E2B_02269098
Linked	E2B_02157007
Linked	E2B_01376292
Linked	
Linked	
Linked	
Linked	E2B_03567130
Linked	
Linked	
Linked	
Linked	
Linked	E2B_03188625
Linked	E2B_03110442
Linked	E2B_02700434
Linked	
Linked	
Linked	E2B_02269098
Linked	E2B_02157007
Linked	E2B_01376292
Linked	
Linked	

Record Type	Link AER** Number
Linked	E2B_03567130
Linked	
Linked	
Linked	
Linked	
Linked	E2B_03188625
Linked	E2B_03110442
Linked	
Linked	
Linked	
Linked	E2B_03567130
Linked	
Linked	
Linked	
Linked	
Linked	E2B_03188625
Linked	E2B_03110442
Linked	E2B_02700434
Linked	
Linked	E2B_02269098
Linked	E2B_02157007
Linked	E2B_01376292
Linked	E2B_01376292

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ADVAIR	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication
AMLODIPINE	Concomitant	Tablets	Unknown				Product used for unknown indication
ASPIRIN	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ATIVAN	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication
BACLOFEN	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication
BIFIDOBACTERIUM ANIMALIS SUBSP. ANIMALIS/LACTOBACILLUS ACIDOPHILUS	Concomitant		Unknown				Product used for unknown indication
CARBAMAZEPINE	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication
COVID-19 VACCINE	Suspect		Unknown				COVID-19 prophylaxis
GABAPENTIN	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication
GRAVOL	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication
IRON	Concomitant		Unknown				Product used for unknown indication
MAGNESIUM	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication
MEPOLIZUMAB	Suspect		Subcutaneous	100.0 Milligram			Asthma
METONIA	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication
MONTELUKAST SODIUM	Concomitant		Unknown				Product used for unknown indication
NIACIN	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication
NICODERM PATCH	Concomitant		Unknown				Product used for unknown indication

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
RISEDRONATE	Concomitant	Tablets	Unknown				Product used for unknown indication
SANDOZ CANDESARTAN PLUS	Concomitant	Tablets	Unknown				Product used for unknown indication
SANDOZ ROSUVASTATIN	Concomitant	Tablets	Unknown				Product used for unknown indication
SPIRIVA	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication
TEVA-PANTOPRAZOLE	Concomitant		Unknown				Product used for unknown indication
TYLENOL ARTHRITIS PAIN 8H	Concomitant	TABLET (EXTENDED-RELEASE)	Unknown				Product used for unknown indication
VENTOLIN	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication
VITAMIN B12	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication
VITAMIN C	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication
VITAMIN D3	Concomitant	Capsules	Unknown				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthritis	v.24.1	
Contusion	v.24.1	
Gait inability	v.24.1	
Hospitalisation	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Intestinal ischaemia	v.24.1	
Multiple sclerosis	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Muscle spasms	v.24.1	
Musculoskeletal disorder	v.24.1	
Vaccination complication	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04105763	0	2021-05-04	2021-05-04	MAH	2021A378270	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04106577	1	2021-05-04	2021-05-12	MAH	2104CAN005384	Study	Other health professional

Serious report?	Death:	Disability:	Congenital Anomaly:
Serious	Yes	No	No
	Life Threatening: No	**Hospitalization:** Yes	**Other Medically Important Conditions:** Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
45 Years	Male			Fatal

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				Product used for unknown indication
PEMBROLIZUMAB	Suspect		Unknown	400.0 Milligram	1 every 6 Weeks		Head and neck cancer metastatic

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Death	v.24.1	
Off label use	v.24.1	
Pneumonia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04106589	0	2021-05-04	2021-05-04	MAH	2021404969	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.24.1	
Drug ineffective	v.24.1	
Malaise	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04106625	0	2021-05-04	2021-05-04	MAH	2021465639	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
63 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
SYNTHROID	Concomitant	NOT SPECIFIED	Oral	0.75 Milligram	1 every 1 Days		Hypothyroidism

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Rash erythematous	v.24.1	
Rash pruritic	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04106641	0	2021-05-04	2021-05-04	MAH	2021469213	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_04107445
Linked	
Linked	E2B_04080768

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arrhythmia	v.24.1	
Dizziness	v.24.1	
Nausea	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04106659	2	2021-05-04	2021-09-23	MAH	2021476377	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
56 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown		Total	1.0 Months	COVID-19 immunisation
INFLIXIMAB	Suspect	NOT SPECIFIED	Intravenous (not otherwise specified)	700.0 Milligram			Colitis ulcerative

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood potassium increased	v.24.1	
COVID-19	v.24.1	
Chest pain	v.24.1	
Cough	v.24.1	
Illness	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Off label use	v.24.1	
Pain	v.24.1	
Pyrexia	v.24.1	
Throat irritation	v.24.1	
Vaccination site pain	v.24.1	
White blood cell count increased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04106663	0	2021-05-04	2021-05-04	MAH	2021465319	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
76 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
DORZOLAMIDE	Concomitant	SOLUTION OPHTHALMIC	Ophthalmic	1.0 Gtt	2 every 1 Days		Glaucoma
ERGOCALCIFEROL	Concomitant		Oral	1000.0 Milligram	1 every 1 Days		Osteoporosis
LATANOPROST	Concomitant	SOLUTION OPHTHALMIC	Ophthalmic	2.5 Milligram	1 every 1 Days		Glaucoma
PANTOPRAZOLE MAGNESIUM	Concomitant		Oral	40.0 Milligram	1 every 1 Days		Gastrooesophageal reflux disease
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
SYNTHROID	Concomitant	NOT SPECIFIED	Oral	0.1 Milligram	1 every 1 Days		Hypothyroidism

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Diarrhoea	v.24.1	1 Days
Dizziness	v.24.1	
Muscular weakness	v.24.1	
Vaccination site pain	v.24.1	1 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04106674	0	2021-05-04	2021-05-04	MAH	2021438820	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
26 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACCUTANE ROCHE	Concomitant	Capsules					
ALYSENA 28	Concomitant	Tablets					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Contusion	v.24.1	
Gait disturbance	v.24.1	
Hyperhidrosis	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Lymphadenopathy	v.24.1	
Malaise	v.24.1	
Ocular hyperaemia	v.24.1	
Pain in extremity	v.24.1	
Pyrexia	v.24.1	
Rheumatoid arthritis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04106683	1	2021-05-04	2021-05-12	MAH	2021436573	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
48 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ALLOPURINOL	Concomitant	Tablets	Oral	200.0 Milligram	every 1 Days		Gout
BUSCOPAN	Concomitant	NOT SPECIFIED	Oral	10.0 Milligram	As required		Prophylaxis
COLCHICINE	Concomitant	Tablets	Oral	6.0 Milligram	As required		Gout
INDAPAMIDE/PERINDOPRIL ERBUMINE	Concomitant		Oral			11.0 Years	Hypertension
PANTOPRAZOLE	Concomitant	NOT SPECIFIED	Oral	40.0 Milligram	every 1 Days		Prophylaxis
PERINDOPRIL	Concomitant		Oral	4.0 Milligram			Hypertension
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ROSUVASTATIN	Concomitant	NOT SPECIFIED	Oral	5.0 Milligram	every 1 Days		Blood cholesterol abnormal
TYLENOL	Concomitant	NOT SPECIFIED	Oral	3.0 Dosage forms	As required		Pain

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Palpitations	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04107020	1	2021-05-04	2021-06-04	MAH	2021-134583	Study	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect						
EYLEA SINGLE-USE VIAL. 2MG/50MCL	Suspect	SOLUTION INTRAVITREAL					Diabetic retinal oedema

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood glucose increased	v.24.1	
Eye haemorrhage	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04107445	0	2021-05-04	2021-05-04	MAH	2021469212	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_04080768
Linked	E2B_04106641

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arrhythmia	v.24.1	
Dizziness	v.24.1	
Nausea	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04108401	1	2021-05-05	2021-05-22	MAH	2021A378160	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
64 Years	Female	165 Centimeter	58 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	1.0 Dosage forms			COVID-19 immunisation
ITRACONAZOLE	Concomitant		Unknown				Onychomycosis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Back pain	v.24.1	
Fatigue	v.24.1	
Muscle contracture	v.24.1	
Musculoskeletal chest pain	v.24.1	
Musculoskeletal stiffness	v.24.1	
Myalgia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04111374	2	2021-05-05	2021-09-08	MAH	2021A382781	Spontaneous	Consumer/other non health professional

Serious report?
Serious

Death:	Yes	**Disability:**	No	**Congenital Anomaly:**	No
Life Threatening:	No	**Hospitalization:**	Yes	**Other Medically Important Conditions:**	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
54 Years	Female			Fatal

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cerebral thrombosis	v.24.1	
Fatigue	v.24.1	
Headache	v.24.1	
Immune thrombocytopenia	v.24.1	
Thrombocytopenia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04111772	0	2021-05-05	2021-05-05	MAH	MYERS SQUIBB COMPANY	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
49 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	
Linked	E2B_04019090

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				COVID-19 prophylaxis
FLOVENT	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication
HYDROXYCHLOROQUINE SULFATE	Concomitant		Unknown				Product used for unknown indication
ORENCIA	Suspect		Subcutaneous	125.0 Milligram	1 every 1 Weeks		Rheumatoid arthritis
ROSUVASTATIN	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
SYNTHROID	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cellulitis	v.24.1	
Myalgia	v.24.1	
Oral herpes	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04111788	3	2021-05-05	2021-07-30	MAH	MYERS SQUIBB COMPANY	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
64 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CANNABIS SATIVA	Concomitant		Unknown				Product used for unknown indication
COVID-19 VACCINE	Suspect		Unknown				Prophylaxis
FOLIC ACID	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication
HYDROXYCHLOROQUINE SULFATE	Concomitant		Unknown				Product used for unknown indication
ORENCIA	Suspect		Intravenous (not otherwise specified)	750.0 Milligram	1 every 4 Weeks		Rheumatoid arthritis
PERINDOPRIL	Concomitant		Unknown				Product used for unknown indication
SYNTHROID	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bone disorder	v.24.1	
Bone pain	v.24.1	
Hepatic cyst	v.24.1	
Musculoskeletal chest pain	v.24.1	
Pancreatic neoplasm	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04111968	2	2021-05-05	2021-05-27	MAH	MYERS SQUIBB COMPANY	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
74 Years	Male	173 Centimeter		Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_04283714

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AMLODIPINE	Concomitant	Tablets	Oral				Hypertension
COVID-19 VACCINE	Suspect		Intramuscular				Product used for unknown indication
ELIQUIS FILM COATED	Suspect	Tablets	Oral	5.0 Milligram	2 every 1 Days		Cerebrovascular accident prophylaxis, COVID-19 prophylaxis
ELIQUIS FILM COATED	Suspect	Tablet	Unknown				Cerebrovascular accident prophylaxis, COVID-19 prophylaxis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04112176	0	2021-05-05	2021-05-05	MAH	2021476435	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Months	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypoaesthesia	v.24.1	
Nausea	v.24.1	
Paraesthesia	v.24.1	
Vertigo	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04112288	2	2021-05-05	2021-06-24	MAH	2021448096	Spontaneous	Physician

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
76 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
DEXILANT	Concomitant	CAPSULE, DELAYED RELEASE	Oral	60.0 Milligram			Gastrooesophageal reflux disease
PANTOPRAZOLE	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
PREGABALIN	Concomitant	Capsules	Oral	225.0 Milligram	2 every 1 Days		Back pain
RESTASIS	Concomitant	EMULSION	Intraocular				Dry eye
TIMOLOL MALEATE/TRAVOPROST	Concomitant		Intraocular				Glaucoma

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Macular oedema	v.24.1	
Retinal vascular thrombosis	v.24.1	
Retinal vein occlusion	v.24.1	
Visual impairment	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04112289	1	2021-05-05	2021-05-17	MAH	2021476322	Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
79 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ADVAIR	Concomitant	NOT SPECIFIED	Inhalation		1 every 1 Days		Asthma
DICLOFENAC	Concomitant		Oral		2 every 1 Days		Arthralgia
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
SPIRIVA	Concomitant	NOT SPECIFIED	Inhalation		1 every 1 Days		Asthma
TYLENOL ARTHRITIS PAIN 8H	Concomitant	TABLET (EXTENDED-RELEASE)	Oral		4 every 1 Days		Arthralgia

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypersensitivity	v.24.1	
Rash pruritic	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04112423	0	2021-05-05	2021-05-05	MAH	2021480361	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04112484	0	2021-05-05	2021-05-05	MAH	2021480251	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
43 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Feeling hot	v.24.1	50 Minutes
Heart rate increased	v.24.1	50 Minutes
Pain in extremity	v.24.1	1 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04112504	1	2021-05-05	2021-05-10	MAH	2021493611	Spontaneous	Consumer/other non health professional

Serious report?		Death:	No	Disability:	No	Congenital Anomaly:	No
Serious		Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
73 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASA	Concomitant	NOT SPECIFIED	Oral	80.0 Milligram			Myocardial infarction
ATORVASTATIN	Concomitant	Tablets	Oral	80.0 Milligram			Hypercholesterolaemia
BRILINTA	Concomitant		Oral	90.0 Milligram	2 every 1 Days		Anticoagulant therapy
DIAZEPAM	Concomitant		Oral	30.0 Milligram			Arthralgia
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
RAMIPRIL	Concomitant	NOT SPECIFIED	Oral	1.2 Milligram	every 1 Days		Hypertension

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Spinal pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04112682	2	2021-05-05	2021-06-03	MAH	2021480629	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
32 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blister	v.24.1	
Disease recurrence	v.24.1	
Hypoaesthesia	v.24.1	
Neuropathy peripheral	v.24.1	
Oral herpes	v.24.1	
Pruritus	v.24.1	
Urticaria	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04112832	1	2021-05-05	2021-05-17	MAH	2021480662	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
74 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
B12 [CYANOCOBALAMIN]	Concomitant		Oral	1000.0 Microgram	1 every 1 Days		Supplementation therapy
EDOXABAN	Concomitant						
ERGOCALCIFEROL	Concomitant		Oral	2000.0 IU (International Unit)			Supplementation therapy
LIXIANA	Concomitant	Tablets	Oral	30.0 Milligram	1 every 1 Days		Anticoagulant therapy
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
TELMISARTAN	Concomitant	Tablets	Oral	40.0 Milligram			Hypertension

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Arthritis	v.24.1	
Burning sensation	v.24.1	
Feeling hot	v.24.1	
Hot flush	v.24.1	52 Minutes
Pruritus	v.24.1	
Thyroiditis	v.24.1	
Urticaria	v.24.1	1 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04112858	1	2021-05-05	2021-05-13	MAH	2021449184	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
74 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
EDOXABAN	Concomitant						Atrial fibrillation
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
TELMISARTAN	Concomitant	Tablets					Blood pressure measurement

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pruritus	v.24.1	
Skin burning sensation	v.24.1	1 Days
Vitamin B12 increased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04112905	2	2021-05-05	2021-07-02	MAH	2021476320	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
32 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
SYNTHROID	Concomitant	NOT SPECIFIED		125.0 Microgram	every 1 Days		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anosmia	v.24.1	
Back pain	v.24.1	
Chest pain	v.24.1	
Cough	v.24.1	
Decreased appetite	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Drug ineffective	v.24.1	
Ear pain	v.24.1	
Headache	v.24.1	
Hypoaesthesia	v.24.1	
Malaise	v.24.1	
Oropharyngeal pain	v.24.1	
Pain in extremity	v.24.1	
Pyrexia	v.24.1	
SARS-CoV-2 test positive	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04112919	0	2021-05-05	2021-05-05	MAH	2021443649	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
52 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ATORVASTATIN	Concomitant	Tablets					
AZOPT	Concomitant	SUSPENSION OPHTHALMIC					
LATANOPROST/TIMOLOL MALEATE	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthritis	v.24.1	6 Days
Asthenia	v.24.1	6 Days
Feeling hot	v.24.1	
Flushing	v.24.1	
Headache	v.24.1	
Hyperhidrosis	v.24.1	
Movement disorder	v.24.1	6 Days
Vaccination site mass	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04112946	2	2021-05-05	2021-07-06	MAH	2021479450	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Pallor	v.24.1	
Syncope	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information

***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04113033	0	2021-05-05	2021-05-05	MAH	2021444582	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
57 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
DEXILANT	Concomitant	CAPSULE, DELAYED RELEASE					
LAMOTRIGINE	Concomitant	Tablets		75.0 Milligram			
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
QUETIAPINE FUMARATE	Concomitant			300.0 Milligram			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.24.1	
Fatigue	v.24.1	
Flushing	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hyperhidrosis	v.24.1	
Loss of personal independence in daily activities	v.24.1	
Lymphadenopathy	v.24.1	
Mental impairment	v.24.1	
Odynophagia	v.24.1	
Paraesthesia	v.24.1	
Skin burning sensation	v.24.1	
Swelling face	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04114156	1	2021-05-06	2021-06-24	MAH	MOD-2021-095503	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
27 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ABILIFY	Concomitant	Tablets		30.0 Milligram	1 every 1 Days		Psychotic disorder
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	1.0 Dosage forms			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Menstruation delayed	v.24.1	
Paranoia	v.24.1	
Psychotic disorder	v.24.1	
Suicidal behaviour	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04117155	0	2021-05-06	2021-05-06	MAH	2105CAN000257	Study	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
40 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				Product used for unknown indication
KEPPRA	Suspect	Tablets	Unknown				Product used for unknown indication
TEMODAL	Suspect	NOT SPECIFIED	Unknown	200.0 Milligram	1 every 1 Days		Glioblastoma multiforme

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Adverse event	v.24.1	
Infection	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Malignant neoplasm progression	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04118098	0	2021-05-06	2021-05-06	MAH	2021479965	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ALTACE	Concomitant	Capsules	Oral	10.0 Milligram	1 every 1 Days		Hypertension
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Vision blurred	v.24.1	
Vitreous floaters	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04118154	0	2021-05-06	2021-05-06	MAH	2021480585	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
85 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AVODART	Concomitant	Capsules	Oral				Prostatomegaly
BISOPROLOL	Concomitant		Oral	5.0 Milligram	1 every 1 Days		Hypertension
ELIQUIS FILM COATED	Concomitant		Oral	2.5 Milligram	2 every 1 Days		Cardiac disorder, Blood disorder
ELIQUIS FILM COATED	Concomitant	Tablets	Oral	2.5 Milligram	2 every 1 Days		Cardiac disorder, Blood disorder
FUROSEMIDE	Concomitant	NOT SPECIFIED	Oral	80.0 Milligram	2 every 1 Days		Fluid retention
INDAPAMIDE	Concomitant	Tablets	Oral	2.5 Milligram	As required		Weight abnormal
PANTOPRAZOLE MAGNESIUM	Concomitant		Oral	40.0 Milligram	1 every 1 Days		Abdominal discomfort

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
ROSUVASTATIN CALCIUM	Concomitant		Oral	5.0 Milligram	every 1 Days		Hypercholesterolaemia
SLOW K	Concomitant	TABLET (EXTENDED-RELEASE)	Oral				Hypokalaemia
TAMSULOSIN	Concomitant	NOT SPECIFIED	Oral	0.4 Milligram			Prostatomegaly

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Gout	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04118185	0	2021-05-06	2021-05-06	MAH	2021445417	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
30 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown				COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Galactostasis	v.24.1	
Mastitis	v.24.1	
Off label use	v.24.1	
Product use issue	v.24.1	
Urticaria	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04118207	1	2021-05-06	2021-06-14	MAH	2021486013	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
50 Years				Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Herpes zoster	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04118213	1	2021-05-06	2021-06-15	MAH	2021465333	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
59 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CELEXA [CELECOXIB]	Concomitant						
DEXILANT	Concomitant	CAPSULE, DELAYED RELEASE					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
RANITIDINE	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Phlebitis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04118245	1	2021-05-06	2021-05-26	MAH	2021456151	Spontaneous	Physician

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
39 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
VENLAFAXINE HYDROCHLORIDE	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Disturbance in attention	v.24.1	
Dizziness	v.24.1	
Fatigue	v.24.1	154 Hours
Feeling abnormal	v.24.1	
Headache	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Tinnitus	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04118434	0	2021-05-06	2021-05-06	MAH	2021456849	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
76 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ELIQUIS FILM COATED	Concomitant	Tablets					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Herpes zoster	v.24.1	
Neuropathy peripheral	v.24.1	3 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04118464	0	2021-05-06	2021-05-06	MAH	2021470311	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
41 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
PROGRAF	Concomitant	NOT SPECIFIED					
SYNTHROID	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Vaginal haemorrhage	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04118550	1	2021-05-06	2021-05-18	MAH	2021458382	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
71 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
SUMATRIPTAN	Concomitant	NOT SPECIFIED		50.0 Milligram	As required		Migraine
TOPIRAMATE	Concomitant	NOT SPECIFIED		50.0 Milligram	every 1 Days		Migraine

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Eye swelling	v.24.1	
Fatigue	v.24.1	
Pruritus	v.24.1	
Rash macular	v.24.1	0 Months

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Swollen tongue	v.24.1	8 Hours

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04118573	0	2021-05-06	2021-05-06	MAH	2021200934	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
31 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest discomfort	v.24.1	2 Hours
Chills	v.24.1	
Connective tissue disorder	v.24.1	
Dyspnoea	v.24.1	2 Hours
Eye swelling	v.24.1	
Fatigue	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypoaesthesia	v.24.1	2 Hours
Hypoaesthesia oral	v.24.1	2 Hours
Influenza like illness	v.24.1	
Myalgia	v.24.1	
Paraesthesia oral	v.24.1	2 Hours
Peripheral swelling	v.24.1	
Pyrexia	v.24.1	
Urticaria	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information

***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04118602	1	2021-05-06	2021-05-28	MAH	2021485975	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
30 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
INSULIN	Concomitant	GLOBULES ORAL					
INSULIN ASPART	Concomitant		Subcutaneous				Diabetes mellitus
PANTOPRAZOLE SODIUM ANHYDROUS	Concomitant		Oral				Gastrooesophageal reflux disease
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
TYLENOL	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood glucose decreased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04118961	1	2021-05-06	2021-05-24	MAH	2021456439	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
50 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
JAMIESON B6	Concomitant						
METHYLCOBALAMIN	Concomitant						
PANTOPRAZOLE	Concomitant	NOT SPECIFIED					
PANTOPRAZOLE MAGNESIUM	Concomitant		Oral	40.0 Milligram			Gastritis
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.24.1	
Defaecation urgency	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dehydration	v.24.1	
Diarrhoea	v.24.1	
Frequent bowel movements	v.24.1	
Gastrointestinal disorder	v.24.1	
Insomnia	v.24.1	
Pyrexia	v.24.1	
Somnolence	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04118969	1	2021-05-06	2021-05-07	MAH	2021458161	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
71 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
HYDROXYCHLOROQUINE SULFATE	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown			1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain upper	v.24.1	
Autoimmune disorder	v.24.1	
Back pain	v.24.1	
Diarrhoea	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	
Inflammation	v.24.1	
Malaise	v.24.1	
Nausea	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04120386	1	2021-05-07	2021-09-14	MAH	2021A389587	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
48 Years	Female	173 Centimeter	73 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Herpes zoster	v.24.1	
Influenza like illness	v.24.1	2 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04120746	1	2021-05-07	2021-06-24	MAH	MOD-2021-101680	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
46 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	1.0 Dosage forms			COVID-19 immunisation
ETHINYL ESTRADIOL/LEVONORGESTREL	Concomitant		Unknown				Contraception

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Flushing	v.24.1	
Pain in extremity	v.24.1	
Superficial vein thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04121072	1	2021-05-07	2021-05-18	MAH	CANSL2021067771	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
49 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				Product used for unknown indication
OTEZLA	Suspect	Tablet	Unknown	30.0 Milligram	2 every 1 Days		Psoriasis
OTEZLA	Suspect	Tablet	Unknown	30.0 Milligram	2 every 1 Days		Psoriasis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Intervertebral disc degeneration	v.24.1	0 Months
Thrombosis	v.24.1	1 Months

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04123116	0	2021-05-07	2021-05-07	MAH	2021TUS003728	Study	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
68 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				Product used for unknown indication
IMMUNOGLOBULIN (HUMAN)	Suspect		Unknown	8.0 Gram	1 every 1 Weeks		Secondary immunodeficiency

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Blood pressure decreased	v.24.1	
Blood pressure increased	v.24.1	
Chills	v.24.1	
Diarrhoea	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Nausea	v.24.1	
Pyrexia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04123881	0	2021-05-07	2021-05-07	MAH	2021456593	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
67 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETYLSALICYLIC ACID	Concomitant			81.0 Milligram			
BRILINTA	Concomitant			90.0 Milligram			
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
VALSARTAN	Concomitant	NOT SPECIFIED		40.0 Milligram			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Cough	v.24.1	
Dyspnoea	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pericardial effusion	v.24.1	
Pleural effusion	v.24.1	
Pyrexia	v.24.1	5 Days
Spinal pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04124211	0	2021-05-07	2021-05-07	MAH	2021458614	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
81 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MICARDIS	Concomitant	Tablets					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
ROSUVASTATIN CALCIUM	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Deafness	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04124279	0	2021-05-07	2021-05-07	MAH	2021498390	Spontaneous	Consumer/other non health professional

Serious report?	Death:	Disability:	Congenital Anomaly:
Serious	Yes	No	No
	Life Threatening: No	**Hospitalization:** No	**Other Medically Important Conditions:** Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
54 Years	Male			Fatal

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Aneurysm	v.24.1	
Cerebral haemorrhage	v.24.1	
Coma	v.24.1	
Death	v.24.1	
Vascular anastomosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04124362	1	2021-05-07	2021-06-17	MAH	2021493258	Spontaneous	Consumer/other non health professional

Serious report?	Death:	Disability:	Congenital Anomaly:
Serious	Yes	No	No
	Life Threatening: No	**Hospitalization:** Yes	**Other Medically Important Conditions:** No

Patient Information

Age	Gender	Height	Weight	Report Outcome
91 Years	Female			Fatal

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pulmonary embolism	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04125742	2	2021-05-08	2021-06-03	MAH	2021493158	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
SYNTHROID	Concomitant	NOT SPECIFIED	Oral	0.05 Milligram			Hypothyroidism

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Hypoaesthesia	v.24.1	
Musculoskeletal stiffness	v.24.1	
Myalgia	v.24.1	
Neck pain	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pain in extremity	v.24.1	
Pain in extremity	v.24.1	
Respiratory disorder	v.24.1	
Vaccination site pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04125765	3	2021-05-08	2021-07-12	MAH	2021465966	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
59 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AMLODIPINE BESILATE	Concomitant						Hypertension
HYDRAZIDE [HYDROCHLOROTHIAZIDE]	Concomitant						Hypertension
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
SYNTHROID	Concomitant	NOT SPECIFIED					Hypothyroidism

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Colitis ischaemic	v.24.1	
Headache	v.24.1	
Pain in extremity	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04127386	3	2021-05-10	2021-06-29	MAH	MOD-2021-101102	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
75 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ATENOLOL	Concomitant	Tablets	Oral	50.0 Milligram			Blood pressure management
AVALIDE	Concomitant	Tablets	Oral	300.0 Milligram			Blood pressure management
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	1.0 Dosage forms			COVID-19 immunisation
GABAPENTIN	Concomitant	NOT SPECIFIED	Oral	400.0 Milligram			Back pain
IRBESARTAN	Concomitant	Tablets	Oral	300.0 Milligram	2 every 1 Days		Blood pressure measurement
MELATONIN	Concomitant	NOT SPECIFIED	Oral	10.0 Milligram	1 every 1 Days		Sleep disorder

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	3 Days
Arthritis	v.24.1	1 Days
Back pain	v.24.1	4 Days
Gait disturbance	v.24.1	4 Days
Pain in extremity	v.24.1	4 Days
SARS-CoV-2 test positive	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04128758	1	2021-05-10	2021-06-24	MAH	MOD-2021-100698	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
70 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	1.0 Dosage forms			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Influenza like illness	v.24.1	
Neck pain	v.24.1	8 Days
Pyrexia	v.24.1	8 Days
Vaccination site cellulitis	v.24.1	8 Days
Vaccination site warmth	v.24.1	8 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04131023	0	2021-05-10	2021-05-10	MAH	2021493329	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
65 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AMLODIPINE	Concomitant	Tablets	Oral	10.0 Milligram	every 1 Days		Hypertension
ATORVASTATIN	Concomitant		Oral	10.0 Milligram	1 every 1 Days		Hypercholesterolaemia
BIFIDOBACTERIUM ANIMALIS SUBSP. LACTIS	Concomitant		Oral				Supplementation therapy
CALCIUM	Concomitant	NOT SPECIFIED	Oral				Supplementation therapy
ERGOCALCIFEROL	Concomitant		Oral		1 every 1 Days		Supplementation therapy
MIRTAZAPINE	Concomitant	Tablets	Oral	7.5 Milligram	1 every 1 Days		Anxiety
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
VITAMIN C	Concomitant		Oral				Supplementation therapy
ZOPICLONE	Concomitant	Tablets	Oral	2.5 Milligram	1 every 1 Days		Sleep disorder

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypoaesthesia	v.24.1	
Paraesthesia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04131050	1	2021-05-10	2021-07-21	MAH	2021466783	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
40 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pain	v.24.1	
Swelling	v.24.1	
Thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04131052	0	2021-05-10	2021-05-10	MAH	2021465647	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
57 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CIPRALEX [ESCITALOPRAM]	Concomitant		Oral	20.0 Milligram	1 every 1 Days		
MELATONIN	Concomitant	NOT SPECIFIED	Oral	5.0 Milligram			
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
VALTREX	Concomitant		Oral	750.0 Milligram	2 every 1 Days		
VITAMIN C [ASCORBIC ACID]	Concomitant			2000.0 Milligram			
VITAMIN D [COLECALCIFEROL]	Concomitant		Oral	1000.0 IU (International Unit)	2 every 1 Days		
WELLBUTRIN XL	Concomitant	TABLET (EXTENDED-RELEASE)	Oral	300.0 Milligram	1 every 1 Days		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Ataxia	v.24.1	
Blood pressure systolic increased	v.24.1	
Eye movement disorder	v.24.1	
Headache	v.24.1	
Vaccination site pain	v.24.1	
Vertigo	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04131064	1	2021-05-10	2021-06-09	MAH	2021467272	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
74 Years	Female		58 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
JARDIANCE	Concomitant						
LIPIDIL	Concomitant	NOT SPECIFIED					
METFORMIN	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Burning sensation	v.24.1	2 Months
Erythema	v.24.1	22110 Minutes
Hypertension	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Insomnia	v.24.1	5 Days
Malaise	v.24.1	18 Days
Peripheral swelling	v.24.1	22110 Minutes
Skin exfoliation	v.24.1	2 Months
Swelling face	v.24.1	22110 Minutes
Urticaria	v.24.1	22110 Minutes

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04131241	2	2021-05-10	2021-06-25	MAH	2021465634	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
49 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
B12 [CYANOCOBALAMIN]	Concomitant	Injection					Vitamin B12 deficiency
GABAPENTIN	Concomitant	NOT SPECIFIED	Oral				Neuropathy peripheral
LYRICA	Concomitant	Capsules	Oral				Neuropathy peripheral
METHYLPREDNISOLONE	Concomitant						Nerve compression
METOPROLOL	Concomitant		Oral				Tachycardia
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Burning sensation	v.24.1	
Limb discomfort	v.24.1	2190 Minutes
Myalgia	v.24.1	
Neuropathy peripheral	v.24.1	2190 Minutes
Pain	v.24.1	
Paraesthesia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04131363	1	2021-05-10	2021-05-11	MAH	2021469423	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
64 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Atrial fibrillation	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04131804	1	2021-05-10	2021-05-27	MAH	2021502271	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
64 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
LUTEINE [PROGESTERONE]	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
VITAMIN D	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.24.1	
Dyspnoea	v.24.1	
Lip swelling	v.24.1	
Mouth swelling	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Paraesthesia oral	v.24.1	
Pharyngeal swelling	v.24.1	
Pruritus	v.24.1	
Respiratory rate increased	v.24.1	
Rhinorrhoea	v.24.1	
Throat tightness	v.24.1	
Wheezing	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04135243	0	2021-05-11	2021-05-11	MAH	2021459486	Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
44 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
IRON	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Eye haemorrhage	v.24.1	
Facial pain	v.24.1	
Headache	v.24.1	
Intraocular pressure increased	v.24.1	
Nausea	v.24.1	
Vision blurred	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04135354	1	2021-05-11	2021-06-25	MAH	2021469963	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
69 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETYLSALICYLIC ACID	Concomitant						
METOPROLOL TARTRATE	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cerebrovascular accident	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04135366	1	2021-05-11	2021-05-20	MAH	2021470475	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Recovered/resolved with sequelae

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.24.1	
Drug ineffective	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04135368	1	2021-05-11	2021-06-25	MAH	2021494117	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
67 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AMLODIPINE	Concomitant	Tablets	Oral				Hypertension
ELIQUIS FILM COATED	Concomitant	Tablets	Oral				Atrial fibrillation
HYDROCHLOROTHIAZIDE	Concomitant	Tablets					Hypertension
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
RAMIPRIL	Concomitant	NOT SPECIFIED	Oral				Hypertension

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	1 Days
Cerebrovascular accident	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.24.1	1 Days
Dysphagia	v.24.1	
Gait disturbance	v.24.1	
Headache	v.24.1	1 Days
Hypoaesthesia	v.24.1	1 Days
Lateral medullary syndrome	v.24.1	
Nausea	v.24.1	1 Days
Speech disorder	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04135370	1	2021-05-11	2021-06-14	MAH	2021470331	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
75 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASA	Concomitant	NOT SPECIFIED	Oral	80.0 Milligram	1 every 1 Days		Metabolic syndrome
CALCIUM	Concomitant	NOT SPECIFIED	Oral		2 every 1 Days		Osteoporosis
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
RISEDRONATE	Concomitant	Tablets		35.0 Milligram	1 every 1 Weeks		Osteoporosis
ROSUVASTATIN CALCIUM	Concomitant		Oral	20.0 Milligram	1 every 1 Days		Dyslipidaemia
SYNTHROID	Concomitant	NOT SPECIFIED	Oral	50.0 Microgram	1 every 1 Days		Hypothyroidism
VITAMIN D3	Concomitant				1 every 1 Weeks		Osteoporosis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Disease recurrence	v.24.1	
Thrombophlebitis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04135373	2	2021-05-11	2021-06-25	MAH	2021503494	Spontaneous	Consumer/other non health professional

Serious report?
Serious

Death:	No	**Disability:**	No	**Congenital Anomaly:**	No
Life Threatening:	No	**Hospitalization:**	No	**Other Medically Important Conditions:**	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
68 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AMLODIPINE BESILATE	Concomitant			5.0 Milligram			Hypertension
DEXLANSOPRAZOLE	Concomitant			60.0 Milligram			Gastrooesophageal reflux disease
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
REMICADE	Suspect	POWDER FOR SOLUTION INTRAVENOUS	Unknown		Cyclical	1.0 Days	Crohn's disease
VALTREX	Concomitant						Oral herpes

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Diarrhoea	v.24.1	
Drug interaction	v.24.1	
Herpes simplex	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04135380	0	2021-05-11	2021-05-11	MAH	2021469756	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Deafness	v.24.1	
Tinnitus	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04135392	2	2021-05-11	2021-06-29	MAH	2021488180	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
20 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
APIXABAN	Concomitant		Oral				Pulmonary embolism
CETIRIZINE HYDROCHLORIDE	Concomitant		Oral				Hypersensitivity
CLOBAZAM	Concomitant	Tablets	Oral				Seizure
EPINEPHRINE HYDROCHLORIDE	Concomitant		Intramuscular				Hypersensitivity
KEPPRA	Concomitant		Oral				Seizure, Epilepsy
KEPPRA	Concomitant	Tablets					Seizure, Epilepsy

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
VENTOLIN [SALBUTAMOL]	Concomitant		Oral				Asthma

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Syncope	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04135393	0	2021-05-11	2021-05-11	MAH	2021503580	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
69 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASA	Concomitant	NOT SPECIFIED	Oral	80.0 Milligram			Prophylaxis
FORMOTEROL FUMARATE/MOMETASONE FUROATE	Concomitant		Inhalation				Dyspnoea
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
ROSUVASTATIN CALCIUM	Concomitant		Oral				Hypercholesterolaemia

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Labyrinthitis	v.24.1	8 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information

***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04135542	3	2021-05-11	2021-07-06	MAH	2021523184	Spontaneous	Physician

Serious report?	Death:	Disability:	Congenital Anomaly:
Serious	Yes	No	No
	Life Threatening: No	**Hospitalization:** No	**Other Medically Important Conditions:** No

Patient Information

Age	Gender	Height	Weight	Report Outcome
72 Years	Female			Fatal

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ATORVASTATIN	Concomitant						Hypercholesterolaemia
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
SERTRALINE HYDROCHLORIDE	Concomitant						Depression

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.24.1	
Myocardial infarction	v.24.1	
Vaccination site pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04135565	0	2021-05-11	2021-05-11	MAH	2021488157	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
43 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bell's palsy	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04136796	0	2021-05-11	2021-05-11	MAH	2021494085	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
67 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AMLODIPINE	Concomitant	Tablets	Oral	2.5 Milligram	1 every 1 Days		Hypertension
D-ALPHA TOCOPHERYL ACETATE/SELENIUM	Concomitant		Oral	2000.0 IU (International Unit)	1 every 1 Days		Vitamin supplementation
PANTOPRAZOLE SODIUM	Concomitant		Oral	40.0 Milligram	1 every 1 Days		Prophylaxis
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
PROLIA PRE-FILLED SYRINGE. PRESERVATIVE-FREE.	Concomitant	SOLUTION SUBCUTANEOUS	Oral				Bone disorder
ROSUVASTATIN CALCIUM	Concomitant		Oral	5.0 Milligram	1 every 1 Days		Hypercholesterolaemia

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Burning sensation	v.24.1	
Hypoaesthesia	v.24.1	
Nasopharyngitis	v.24.1	
Paraesthesia	v.24.1	
Trigeminal nerve disorder	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04141805	0	2021-05-12	2021-05-12	MAH	2021514643	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pulmonary embolism	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04141840	1	2021-05-12	2021-05-20	MAH	2021488156	Spontaneous	Physician

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
41 Years	Female			Recovered/resolved with sequelae

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Burning sensation	v.24.1	-16
Electric shock sensation	v.24.1	-16
Hypoaesthesia	v.24.1	-16
Pain in extremity	v.24.1	
Paraesthesia	v.24.1	
Sensory loss	v.24.1	
Sleep disorder	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Small fibre neuropathy	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04141872	0	2021-05-12	2021-05-12	MAH	2021503665	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
88 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pneumonia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04141925	0	2021-05-12	2021-05-12	MAH	2021514658	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
74 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Condition aggravated	v.24.1	
Deafness	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04142149	1	2021-05-12	2021-06-25	MAH	2021480527	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
74 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Deafness neurosensory	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04142278	1	2021-05-12	2021-07-05	MAH	2021487854	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
60 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Angioedema	v.24.1	
Face oedema	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04143654	0	2021-05-12	2021-05-12	MAH	2021514666	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
23 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blister	v.24.1	
Herpes zoster	v.24.1	
Scar	v.24.1	
Vision blurred	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04145310	1	2021-05-13	2021-06-24	MAH	MOD-2021-114288	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
54 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETAMINOPHEN	Concomitant	NOT SPECIFIED	Oral	500.0 Milligram			Product used for unknown indication
ACETYLSALICYLIC ACID	Concomitant		Oral	81.0 Milligram	4 every 1 Days		Product used for unknown indication
ALENDRONATE SODIUM	Concomitant			70.0 Milligram	1 every 1 Weeks		Product used for unknown indication
ATORVASTATIN	Concomitant		Oral	20.0 Milligram	4 every 1 Days		Product used for unknown indication
CANDESARTAN	Concomitant		Oral	8.0 Milligram	4 every 1 Days		Product used for unknown indication

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CETIRIZINE	Concomitant		Oral	10.0 Milligram			Product used for unknown indication
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	1.0 Dosage forms			COVID-19 immunisation
DIPHENHYDRAMINE	Concomitant		Oral	25.0 Milligram			Product used for unknown indication
GLICLAZIDE	Concomitant		Oral	60.0 Milligram	2 every 1 Days		Product used for unknown indication
INSULIN GLARGINE	Concomitant				1 every 1 Hours		Product used for unknown indication
LETROZOLE	Concomitant		Oral	2.5 Milligram	4 every 1 Days		Product used for unknown indication
METFORMIN	Concomitant		Oral	500.0 Milligram	2 every 1 Days		Product used for unknown indication
OMEPRAZOLE	Concomitant		Oral	20.0 Milligram	2 every 1 Days		Product used for unknown indication
SITAGLIPTIN PHOSPHATE	Concomitant		Oral	100.0 Milligram	4 every 1 Days		Product used for unknown indication
VIT D [COLECALCIFEROL]	Concomitant		Oral	1000.0 Dosage forms	4 every 1 Days		Product used for unknown indication
VITAMIN B12	Concomitant		Oral	250.0 Milligram	4 every 1 Days		Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Deafness	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04148436	1	2021-05-13	2021-06-01	MAH	2021487052	Spontaneous	Physician

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
48 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ALLOPURINOL	Concomitant						
AMITRIPTYLINE	Concomitant						Migraine, Insomnia
D-ALPHA TOCOPHEROL	Concomitant						
LORATADINE	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
PYRIDOXINE HYDROCHLORIDE	Concomitant						
SERTRALINE HYDROCHLORIDE	Concomitant						Anxiety
XANAX	Concomitant	Tablets					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pericarditis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04148446	1	2021-05-13	2021-06-24	MAH	2021524257	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
64 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Herpes ophthalmic	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04148450	0	2021-05-13	2021-05-13	MAH	2021498013	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
33 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BETA-CAROTENE/BIOTIN/CALCIUM/CHROMIUM/COPPER/FOLIC ACID/IODINE/IRON/MAGNESIUM/MANGANESE/MOLYBDENUM/NICOTINAMIDE/PANTOTHENIC ACID/PYRIDOXINE HYDROCHLORIDE/RIBOFLAVIN/SELENIUM/VITAMIN A/VITAMIN B1/VITAMIN B12/VITAMIN C/VITAMIN D/VITAMIN E/VITAMIN K1/ZINC	Concomitant						
CALCIUM CARBONATE	Concomitant						

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Exposure during pregnancy	v.24.1	
Off label use	v.24.1	
Product use issue	v.24.1	
Vaginal haemorrhage	v.24.1	1 Months

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04149657	0	2021-05-13	2021-05-13	MAH	2021486972	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
57 Years	Female			Recovered/resolved with sequelae

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Arthritis	v.24.1	
Diverticulitis	v.24.1	-76
Eating disorder	v.24.1	
Erythema	v.24.1	
Gait disturbance	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hyperaesthesia teeth	v.24.1	
Impaired driving ability	v.24.1	
Insomnia	v.24.1	
Joint swelling	v.24.1	
Musculoskeletal stiffness	v.24.1	
Pain in extremity	v.24.1	
Peripheral swelling	v.24.1	
Vertigo	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04152888	1	2021-05-14	2021-09-14	MAH	2021A416820	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
40 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Platelet count decreased	v.24.1	
Thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04153984	1	2021-05-14	2021-05-24	MAH	2021497655	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
62 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
SYNTHROID	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Communication disorder	v.24.1	
Hypoaesthesia	v.24.1	
Mobility decreased	v.24.1	
Nightmare	v.24.1	
Vaccination site pain	v.24.1	
Vaccination site reaction	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Vaccination site swelling	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04153992	2	2021-05-14	2021-07-01	MAH	2021503848	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
66 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_04154489
Linked	E2B_04154489
Linked	
Linked	E2B_04154489
Linked	E2B_04154489

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MELOXICAM	Concomitant	NOT SPECIFIED					Psoriatic arthropathy
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthritis reactive	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Synovitis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04154070	0	2021-05-14	2021-05-14	MAH	2021522297	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
66 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypertension	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04154096	1	2021-05-14	2021-05-26	MAH	2021487337	Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
71 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Angioedema	v.24.1	
Candida infection	v.24.1	
Condition aggravated	v.24.1	
Dermatitis	v.24.1	
Eye pruritus	v.24.1	
Seasonal allergy	v.24.1	
Sneezing	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04154221	0	2021-05-14	2021-05-14	MAH	2021502311	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
53 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Sudden hearing loss	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04154267	1	2021-05-14	2021-06-30	MAH	2021502676	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
30 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ETHINYL ESTRADIOL/NORETHINDRONE ACETATE	Concomitant						
LAMOTRIGINE	Concomitant	Tablets					
LYRICA	Concomitant	Capsules					
NAPROXEN	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
SERTRALINE HYDROCHLORIDE	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypoaesthesia	v.24.1	
Hypoaesthesia oral	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04154270	0	2021-05-14	2021-05-14	MAH	2021488124	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
35 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Total	1.0 Days	COVID-19 immunisation
VENLAFAXINE HYDROCHLORIDE	Concomitant			75.0 Milligram			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	
Hyperhidrosis	v.24.1	
Loss of consciousness	v.24.1	
Malaise	v.24.1	
Neurogenic shock	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04154331	1	2021-05-14	2021-05-26	MAH	2021522272	Spontaneous	Consumer/other non health professional

Serious report?
Serious

Death:	No	Disability:	No	Congenital Anomaly:	No
Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
79 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AMLODIPINE	Concomitant	Tablets	Oral	5.0 Milligram		12.0 Years	Hypertension
EZETIMIBE	Concomitant	Tablets	Oral	10.0 Milligram			Hypercholesterolaemia
METFORMIN	Concomitant		Oral	500.0 Milligram	2 every 1 Days		Type 2 diabetes mellitus
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood pressure fluctuation	v.24.1	27 Days
Hypertension	v.24.1	27 Days
Malaise	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04154332	1	2021-05-14	2021-06-24	MAH	2021503902	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
85 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_04154489
Linked	E2B_04154489
Linked	E2B_04154489
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
HYDROXYCHLOROQUINE SULFATE	Concomitant						Rheumatoid arthritis
METHOTREXATE	Concomitant	NOT SPECIFIED					Rheumatoid arthritis
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Arthritis	v.24.1	
Inflammatory pain	v.24.1	
Pain in extremity	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04154334	1	2021-05-14	2021-06-24	MAH	2021503911	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
49 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_04154489
Linked	
Linked	E2B_04154489
Linked	E2B_04154489

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
HYDROXYCHLOROQUINE SULFATE	Concomitant						Rheumatoid arthritis
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain upper	v.24.1	-56
Arthritis	v.24.1	-57

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.24.1	-56
Neutropenia	v.24.1	
Pain in extremity	v.24.1	-56
Synovitis	v.24.1	
Tendon disorder	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04154341	1	2021-05-14	2021-06-24	MAH	2021503860	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
76 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_04154489
Linked	E2B_04154489
Linked	E2B_04154489
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ARAVA	Concomitant	Tablets					Rheumatoid arthritis
HYDROXYCHLOROQUINE SULFATE	Concomitant						Rheumatoid arthritis
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Arthritis	v.24.1	
Joint stiffness	v.24.1	
Malaise	v.24.1	
Musculoskeletal stiffness	v.24.1	
Peripheral swelling	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04154489	1	2021-05-14	2021-06-29	MAH	2021503784	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
67 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_04153992
Linked	E2B_04154341
Linked	E2B_04153992
Linked	E2B_04153992
Linked	E2B_04154332
Linked	E2B_04154341
Linked	E2B_04154334
Linked	E2B_04154334
Linked	E2B_04154332
Linked	E2B_04154341
Linked	E2B_04153992
Linked	E2B_04154334
Linked	E2B_04154332

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
PREDNISONE	Concomitant	NOT SPECIFIED		5.0 Milligram			Psoriatic arthropathy
PROLIA PRE-FILLED SYRINGE. PRESERVATIVE-FREE.	Concomitant	SOLUTION SUBCUTANEOUS	Subcutaneous				Osteoporosis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Arthritis	v.24.1	
Joint swelling	v.24.1	
Joint warmth	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04154512	1	2021-05-14	2021-06-23	MAH	2021541037	Spontaneous	Physician

Serious report?	Death:	Disability:	Congenital Anomaly:
Serious	Yes	No	No
	Life Threatening: No	**Hospitalization:** No	**Other Medically Important Conditions:** No

Patient Information

Age	Gender	Height	Weight	Report Outcome
58 Years	Female			Fatal

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETYLSALICYLIC ACID	Concomitant						
ATORVASTATIN CALCIUM	Concomitant	Tablets					
B12 [CYANOCOBALAMIN]	Concomitant						
CALCIUM [CALCIUM CARBONATE]	Concomitant						
GLICLAZIDE	Concomitant	Tablets					
JANUVIA	Concomitant	NOT SPECIFIED	Unknown				
METFORMIN	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
VITAMIN D	Concomitant	NOT SPECIFIED					
ZOPICLONE	Concomitant	Tablets					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Sudden death	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04156351	1	2021-05-16	2021-07-19	MAH	2021529824	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
72 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Acne	v.24.1	
Burning sensation	v.24.1	
Erythema	v.24.1	
Feeling hot	v.24.1	
Hypersensitivity	v.24.1	
Joint swelling	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Musculoskeletal stiffness	v.24.1	
Swelling	v.24.1	
Thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04161409	0	2021-05-17	2021-05-17	MAH	2021470011	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
59 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Balance disorder	v.24.1	
Dizziness	v.24.1	
Feeling drunk	v.24.1	
Gait disturbance	v.24.1	
Neurological symptom	v.24.1	
Vertigo	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04161432	1	2021-05-17	2021-06-29	MAH	2021494276	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
44 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AMLODIPINE	Concomitant	Tablets		5.0 Milligram			
PERINDOPRIL	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Herpes zoster	v.24.1	
Ophthalmic herpes zoster	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04161448	2	2021-05-17	2021-06-29	MAH	2021494848	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
47 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain upper	v.24.1	
Hunger	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04161452	0	2021-05-17	2021-05-17	MAH	2021530369	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
74 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BREO ELLIPTA	Concomitant	INHALATION	Inhalation		1 every 1 Days		Chronic obstructive pulmonary disease
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
SPIRIVA	Concomitant	NOT SPECIFIED	Inhalation		1 every 1 Days		Chronic obstructive pulmonary disease

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
VENTOLIN [SALBUTAMOL]	Concomitant		Inhalation		As required		Chronic obstructive pulmonary disease

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Deafness unilateral	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04161492	1	2021-05-17	2021-05-28	MAH	2021540472	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
73 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AMLODIPINE BESILATE	Concomitant						
ASA	Concomitant	NOT SPECIFIED					
ATACAND	Concomitant	Tablets					
BISOPROLOL	Concomitant						
CLOPIDOGREL BISULFATE	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
PRAVASTATIN	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Burning sensation	v.24.1	
Cardiac flutter	v.24.1	
Headache	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04161521	1	2021-05-17	2021-05-26	MAH	2021494053	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
74 Years	Female	165 Centimeter	61 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CYANOCOBALAMIN	Concomitant		Intramuscular				Pernicious anaemia
IRON	Concomitant		Oral				Supplementation therapy
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arrhythmia	v.24.1	
Condition aggravated	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Contusion	v.24.1	
Tachycardia	v.24.1	
Thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04161529	1	2021-05-17	2021-05-26	MAH	2021493166	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
43 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
IBUPROFEN	Concomitant		Oral	400.0 Milligram		1.0 Days	Headache
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cardiac flutter	v.24.1	18 Hours

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04161533	0	2021-05-17	2021-05-17	MAH	2021529179	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
6 Decade	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACTEMRA	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.24.1	
Malaise	v.24.1	
Pain in extremity	v.24.1	
Photosensitivity reaction	v.24.1	
Pyrexia	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Rash macular	v.24.1	
Rash vesicular	v.24.1	
Sinus pain	v.24.1	
Skin burning sensation	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04161548	2	2021-05-17	2021-06-29	MAH	2021494191	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
68 Years	Female			Recovered/resolved with sequelae

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CALCIUM	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	-104
C-reactive protein increased	v.24.1	-90
Chills	v.24.1	-104
Headache	v.24.1	-101
Headache	v.24.1	-104

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Limb discomfort	v.24.1	-104
Myalgia	v.24.1	-104
Platelet count increased	v.24.1	-90
Portal vein thrombosis	v.24.1	-90
Pyrexia	v.24.1	-104
Vision blurred	v.24.1	-101
White blood cell count increased	v.24.1	-90

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04161583	3	2021-05-17	2021-08-04	MAH	2021493527	Spontaneous	Physician

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
33 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arrhythmia	v.24.1	
Chest discomfort	v.24.1	
Cold sweat	v.24.1	
Decreased appetite	v.24.1	
Dyspnoea	v.24.1	
Fatigue	v.24.1	
Loss of consciousness	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Palpitations	v.24.1	
Syncope	v.24.1	
Tachycardia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04161585	1	2021-05-17	2021-06-30	MAH	2021503889	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
85 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Months	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cardiac arrest	v.24.1	0
Thrombosis	v.24.1	0

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04161613	1	2021-05-17	2021-05-20	MAH	2021494812	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
29 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AMITRIPTYLINE	Concomitant						
LEVOTHYROXINE SODIUM	Concomitant	NOT SPECIFIED	Unknown				
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood pressure orthostatic abnormal	v.24.1	
Confusional state	v.24.1	
Dizziness	v.24.1	
Heart rate increased	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Heart rate irregular	v.24.1	
Hypotension	v.24.1	
Palpitations	v.24.1	
Postural orthostatic tachycardia syndrome	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04161628	2	2021-05-17	2021-06-17	MAH	2021498895	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
48 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
SYNTHROID 137	Concomitant		Oral				Hypothyroidism

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Chest pain	v.24.1	
Chest pain	v.24.1	
Pain	v.24.1	
Pericarditis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04161662	3	2021-05-17	2021-07-01	MAH	2021533513	Spontaneous	Consumer/other non health professional

Serious report?
Serious

Death:	No	**Disability:**	No	**Congenital Anomaly:**	No
Life Threatening:	Yes	**Hospitalization:**	No	**Other Medically Important Conditions:**	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
57 Years	Male		91 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	000949686

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ALOXIPRIN	Concomitant				As required		Myocardial infarction
ATIVAN	Concomitant	NOT SPECIFIED	Sublingual	1.0 Milligram			
ATORVASTATIN	Concomitant			40.0 Milligram	1 every 1 Days		
BENZYDAMINE HYDROCHLORIDE	Concomitant						Oropharyngeal pain, Candida infection
BISOPROLOL FUMARATE	Concomitant			2.5 Milligram	2 every 1 Days		
BUDESONIDE/FORMOTEROL FUMARATE	Concomitant				2 every 1 Days		
CICLESONIDE	Concomitant	NOT SPECIFIED	Intra-nasal		1 every 1 Days		
DIGOXIN	Concomitant	NOT SPECIFIED		0.125 Milligram	1 every 1 Days		
ELIQUIS FILM COATED	Concomitant	Tablets		5.0 Milligram	2 every 1 Days		

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
FUROSEMIDE	Concomitant	NOT SPECIFIED		30.0 Milligram	1 every 1 Days		
MONTELUKAST SODIUM	Concomitant			10.0 Milligram	1 every 1 Days		
NITROGLYCERIN	Concomitant		Sublingual				
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
VENTOLIN [SALBUTAMOL]	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain upper	v.24.1	
Anxiety	v.24.1	
Arrhythmia	v.24.1	
Asthma	v.24.1	
Chest pain	v.24.1	
Chills	v.24.1	5925 Minutes
Choking	v.24.1	60 Hours
Deafness	v.24.1	9 Days
Delirium	v.24.1	
Dizziness	v.24.1	
Dizziness	v.24.1	
Dysgeusia	v.24.1	
Dysphagia	v.24.1	
Dyspnoea	v.24.1	
Ear discomfort	v.24.1	
Ear discomfort	v.24.1	5925 Minutes
Eye pain	v.24.1	
Eye pain	v.24.1	
Fatigue	v.24.1	
Fatigue	v.24.1	16005 Minutes
Feeling hot	v.24.1	
Hiccups	v.24.1	48 Hours
Hyperhidrosis	v.24.1	
Hypersensitivity	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hyperventilation	v.24.1	
Myalgia	v.24.1	
Nervousness	v.24.1	
Ocular discomfort	v.24.1	
Pain in extremity	v.24.1	
Pain in extremity	v.24.1	4 Days
Panic attack	v.24.1	
Pyrexia	v.24.1	16005 Minutes
Sensory loss	v.24.1	
Syncope	v.24.1	
Throat irritation	v.24.1	
Throat tightness	v.24.1	60 Hours
Tinnitus	v.24.1	5925 Minutes
Toothache	v.24.1	4 Days
Vaccination site pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04165087	1	2021-05-18	2021-06-15	MAH	CA2021AMR071552	Study	Consumer/other non health professional

Serious report?
Serious

Death:	No	**Disability:**	No	**Congenital Anomaly:**	No
Life Threatening:	No	**Hospitalization:**	Yes	**Other Medically Important Conditions:**	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
83 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	E2B_02406050
Linked	
Linked	E2B_02529330
Linked	E2B_03160344
Linked	
Linked	
Linked	
Linked	E2B_02406050
Linked	
Linked	
Linked	E2B_02529330
Linked	E2B_03160344
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				COVID-19 prophylaxis
HUMIRA	Suspect	SOLUTION SUBCUTANEOUS	Unknown				Product used for unknown indication
MEPOLIZUMAB	Suspect		Subcutaneous	100.0 Milligram			Asthma

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Breast cancer	v.24.1	
Drug hypersensitivity	v.24.1	
Eye disorder	v.24.1	
Eye pain	v.24.1	
Eye swelling	v.24.1	
Hypersensitivity	v.24.1	
Lacrimation increased	v.24.1	
Pyrexia	v.24.1	
Sepsis	v.24.1	
Swelling face	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04166320	2	2021-05-18	2021-09-06	MAH	2021498856	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
58 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.24.1	
Dizziness	v.24.1	
Dysgeusia	v.24.1	281 Hours
Fatigue	v.24.1	
Myalgia	v.24.1	281 Hours
Pain in extremity	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Swelling	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04166327	0	2021-05-18	2021-05-18	MAH	2021540763	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
31 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
FLOVENT	Concomitant	NOT SPECIFIED					
NAPROXEN	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
VITAMIN D	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Back pain	v.24.1	
Headache	v.24.1	
Hypoaesthesia	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Lymphadenopathy	v.24.1	
Muscle spasms	v.24.1	
Paraesthesia	v.24.1	
Peripheral coldness	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04166348	1	2021-05-18	2021-06-01	MAH	2021503407	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
92 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
APO HYDRO	Concomitant	Tablets					
CALCIUM CARBONATE/VITAMIN D3	Concomitant						
METOPROLOL	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
POTASSIUM CHLORIDE	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood pressure decreased	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	
Headache	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Loss of consciousness	v.24.1	10 Minutes
Off label use	v.24.1	
Syncope	v.24.1	10 Minutes
Unresponsive to stimuli	v.24.1	10 Minutes

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04166359	4	2021-05-18	2021-08-23	MAH	2021547048	Spontaneous	Consumer/other non health professional

Serious report?	Death:	Yes	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
65 Years	Female			Fatal

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETYLSALICYLIC ACID	Concomitant				1 every 1 Days		
ALTACE	Concomitant	Capsules			every 1 Days		
BACLOFEN	Concomitant	NOT SPECIFIED					
BISOPROLOL	Concomitant			5.0 Milligram	every 1 Days		
CLONAZEPAM	Concomitant	Tablets					
COAL TAR/RESORCINOL MONOACETATE	Concomitant				every 1 Days		
DILANTIN [PHENYTOIN]	Concomitant			50.0 Milligram	3 every 1 Days		
FUROSEMIDE/POTASSIUM CHLORIDE	Concomitant			40.0 Milligram	every 1 Days		
LOVENOX [LEVOFLOXACIN]	Concomitant						
METOCLOPRAMIDE	Concomitant			10.0 Milligram	3 every 1 Days		

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
METRONIDAZOLE BENZOATE	Concomitant						
MORPHINE	Concomitant	NOT SPECIFIED		10.0 Milligram	3 every 1 Days		
NABILONE	Concomitant	NOT SPECIFIED		2.0 Milligram	2 every 1 Days		
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
PRAMIPEXOLE DIHYDROCHLORIDE	Concomitant			0.5 Milligram	every 1 Days		
PREGABALIN	Concomitant			300.0 Milligram	2 every 1 Days		
ROSUVASTATIN CALCIUM	Concomitant			5.0 Milligram	every 1 Days		
SENOKOT	Concomitant	Tablet					
TIOTROPIUM BROMIDE	Concomitant						
TRANSDERMAL NICOTINE PATCH	Concomitant	PATCH					
TRAZODONE HYDROCHLORIDE	Concomitant			200.0 Milligram			
XARELTO	Concomitant	Coated tablet					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Atrial fibrillation	v.24.1	
Blood pressure decreased	v.24.1	
Cardiac valve disease	v.24.1	
Dyspnoea	v.24.1	
Haemorrhagic stroke	v.24.1	
Myocardial infarction	v.24.1	
Pain in extremity	v.24.1	
Pulmonary oedema	v.24.1	
Septic shock	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04166368	1	2021-05-18	2021-07-05	MAH	2021498800	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
74 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CANDESARTAN	Concomitant						
CANNABIS SATIVA	Concomitant						
CURCUMIN	Concomitant	Capsule					
METFORMIN	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cerebrovascular accident	v.24.1	-90

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04166389	0	2021-05-18	2021-05-18	MAH	2021530546	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
40 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AMITRIPTYLINE	Concomitant			25.0 Milligram			Depression, Anxiety
CONCERTA	Concomitant	TABLET (EXTENDED-RELEASE)		27.0 Milligram			Disturbance in attention
ERGOCALCIFEROL	Concomitant				1 every 1 Weeks		
INSULIN	Concomitant	GLOBULES ORAL					Diabetes mellitus
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown			1.0 Days	COVID-19 immunisation
SYNTHROID	Concomitant	NOT SPECIFIED		125.0 Microgram			Thyroid disorder

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
TEVA-DULOXETINE	Concomitant	NOT SPECIFIED		30.0 Milligram			Depression, Anxiety

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Autoimmune disorder	v.24.1	2 Months
Dysphagia	v.24.1	2 Months
Ear swelling	v.24.1	2 Months
Peripheral swelling	v.24.1	2 Months
Pharyngeal swelling	v.24.1	2 Months

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04166394	2	2021-05-18	2021-07-11	MAH	2021499354	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
66 Years	Male	178 Centimeter	92 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ATENOLOL	Concomitant	Tablets		25.0 Milligram	every 1 Days		Hypertension
LIFITEGRAST	Concomitant	Eye drops					Dry eye
PANTOLOC [PANTOPRAZOLE]	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
SYNTHROID	Concomitant	NOT SPECIFIED					Thyroid disorder

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pruritus	v.24.1	1 Months

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Urticaria	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04166408	1	2021-05-18	2021-05-28	MAH	2021548335	Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
61 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CETIRIZINE	Concomitant						
CICLESONIDE	Concomitant	NOT SPECIFIED					
DIPHENHYDRAMINE	Concomitant						
EPINEPHRINE	Concomitant	NOT SPECIFIED	Intramuscular				
FLUOXETINE	Concomitant	NOT SPECIFIED					
HUMAN C1 ESTERASE INHIBITOR	Concomitant						
HYOSCINE BUTYLBROMIDE	Concomitant						
IMMUNOGLOBULIN G (HUMAN)	Concomitant						
METHYLPREDNISOLONE	Concomitant						
MONTELUKAST	Concomitant	NOT SPECIFIED					

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain	v.24.1	
Chest discomfort	v.24.1	
Dyspnoea	v.24.1	
Idiopathic angioedema	v.24.1	
Laryngeal oedema	v.24.1	
Nausea	v.24.1	
Swelling	v.24.1	
Swollen tongue	v.24.1	
Tachycardia	v.24.1	
Wheezing	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04167736	2	2021-05-18	2021-06-29	MAH	2021499944	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
32 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MOVISSE	Concomitant	Tablets	Oral		1 every 1 Days		Contraception
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.24.1	
Fatigue	v.24.1	
Feeling drunk	v.24.1	
Feeling hot	v.24.1	
Gait disturbance	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypoaesthesia	v.24.1	
Impaired driving ability	v.24.1	
Miosis	v.24.1	
Muscle rigidity	v.24.1	
Nausea	v.24.1	
Paraesthesia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04167751	1	2021-05-18	2021-06-04	MAH	2021502592	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
70 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
C-reactive protein increased	v.24.1	
Pericardial effusion	v.24.1	
Pericarditis	v.24.1	-104
Pleural effusion	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04168477	5	2021-05-18	2021-07-13	MAH	2021529566	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
74 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ANDRIOL	Concomitant	Capsules	Oral	40.0 Milligram	every 1 Days		Androgen deficiency
FLAREX	Concomitant	SUSPENSION OPHTHALMIC	Intraocular	0.01 Percent			Corneal transplant
OMNARIS	Concomitant	SPRAY, METERED DOSE	Intra-nasal				Seasonal allergy
PARIET	Concomitant	TABLET (ENTERIC-COATED)	Oral	10.0 Milligram	2 every 1 Days		Gastrooesophageal reflux disease
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
PREDNISONE	Concomitant	NOT SPECIFIED		0.012 Percent	every 1 Days		

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
RABEPRAZOLE	Concomitant		Oral				Gastrooesophageal reflux disease

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Accident	v.24.1	
Arthralgia	v.24.1	
Back injury	v.24.1	
Back pain	v.24.1	
Blood iron decreased	v.24.1	
Herpes zoster	v.24.1	
Insomnia	v.24.1	
Muscular weakness	v.24.1	
Myalgia	v.24.1	
Pain	v.24.1	-98
Spinal deformity	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04168481	0	2021-05-18	2021-05-18	MAH	2021497589	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
63 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETYLSALICYLIC ACID	Concomitant						
AMLODIPINE BESILATE	Concomitant						
ESOMEPRAZOLE SODIUM	Concomitant						
EZETROL	Concomitant	Tablets					
LANTUS	Concomitant	SOLUTION SUBCUTANEOUS					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Months	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.24.1	
Disease recurrence	v.24.1	
Dyspnoea	v.24.1	
Fatigue	v.24.1	
Hypertension	v.24.1	
Illness	v.24.1	
Myocarditis	v.24.1	
Pyrexia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04168496	0	2021-05-18	2021-05-18	MAH	2021530433	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
70 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CELEBREX	Concomitant	Capsules	Oral	200.0 Milligram			Pain, Arthritis
CIPRALEX [ESCITALOPRAM]	Concomitant		Oral	20.0 Milligram	1 every 1 Days		Depression
LIOTHYRONINE SODIUM	Concomitant		Oral		3 every 1 Days		Pain
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				COVID-19 immunisation
PREVACID	Concomitant	NOT SPECIFIED	Oral	20.0 Milligram	2 every 1 Days		Reflux gastritis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pulmonary embolism	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04168709	2	2021-05-18	2021-07-01	MAH	2021530358	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
71 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
FLUOXETINE	Concomitant	NOT SPECIFIED	Oral				Depression
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
SYNTHROID	Concomitant	NOT SPECIFIED	Oral				Hypothyroidism
VITAMIN C [ASCORBIC ACID]	Concomitant		Oral				Vitamin supplementation
VITAMIN D [COLECALCIFEROL]	Concomitant		Oral				Vitamin supplementation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arrhythmia	v.24.1	
Dyspnoea	v.24.1	
Fatigue	v.24.1	
Hypoaesthesia	v.24.1	1 Days
Palpitations	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04168925	2	2021-05-18	2021-06-30	MAH	2021499484	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
44 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
DIAZEPAM	Concomitant	NOT SPECIFIED					
IBUPROFEN	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
TYLENOL	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Heavy menstrual bleeding	v.24.1	
Menstruation irregular	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04169024	2	2021-05-18	2021-06-15	MAH	2021498959	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
47 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood iron decreased	v.24.1	
Dysmenorrhoea	v.24.1	
Heavy menstrual bleeding	v.24.1	-117
Menstruation irregular	v.24.1	
Vaginal haemorrhage	v.24.1	
White blood cell count increased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04169337	2	2021-05-18	2021-08-09	MAH	20210520890	Study	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
42 Years	Male		103 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AZATHIOPRINE	Concomitant	Tablets	Oral	150.0 Milligram	1 every 1 Days		Colitis ulcerative
COVID-19 VACCINE	Suspect		Unknown				Immunisation
COVID-19 VACCINE	Suspect	Unknown	Unknown				Immunisation
REMICADE	Suspect	Solution for infusion	Intravenous (not otherwise specified)	5.0 mg/kg	1 every 6 Weeks		Colitis ulcerative
REMICADE	Suspect	POWDER FOR SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	500.0 Milligram	1 every 8 Weeks		Colitis ulcerative

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal discomfort	v.24.1	3 Months
Bone pain	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Defaecation urgency	v.24.1	
Diarrhoea	v.24.1	
Frequent bowel movements	v.24.1	3 Months
Haematochezia	v.24.1	
Off label use	v.24.1	
Product use issue	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04172376	0	2021-05-19	2021-05-19	MAH	2021540814	Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
47 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
LOSARTAN	Concomitant			50.0 Milligram			
LOZIDE [INDAPAMIDE]	Concomitant			1.25 Milligram			
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
VITAMIN D	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest discomfort	v.24.1	2 Days
Chest pain	v.24.1	2 Days
Eye pain	v.24.1	2 Days
Fatigue	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.24.1	2 Days
Malaise	v.24.1	
Pain in extremity	v.24.1	3 Days
Palpitations	v.24.1	2 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04172394	1	2021-05-19	2021-08-19	MAH	2021535996	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
67 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
XARELTO	Concomitant	Coated tablet	Oral				Thrombosis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Erythema	v.24.1	
Pain in extremity	v.24.1	
Peripheral swelling	v.24.1	
Thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04172430	0	2021-05-19	2021-05-19	MAH	2021503287	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
40 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood glucose decreased	v.24.1	
Loss of consciousness	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04172465	0	2021-05-19	2021-05-19	MAH	CA2021AMR073282	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	
Linked	E2B_02026708
Linked	
Linked	E2B_01077319
Linked	
Linked	
Linked	E2B_02582180

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BUDESONIDE/FORMOTEROL FUMARATE	Suspect		Unknown				Product used for unknown indication
COVID-19 VACCINE	Suspect		Unknown				Prophylaxis
MEPOLIZUMAB	Suspect		Subcutaneous	100.0 Milligram			Asthma

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Appendicitis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04172473	2	2021-05-19	2021-06-14	MAH	CA2021AMR092296	Study	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
64 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				COVID-19 prophylaxis
MEPOLIZUMAB	Suspect	Solution for injection in pre-filled pen	Unknown	100.0 Milligram			Product used for unknown indication, Asthma

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MEPOLIZUMAB	Suspect	Solution for injection in pre-filled pen	Subcutaneous	100.0 Milligram			Product used for unknown indication, Asthma
MEPOLIZUMAB	Suspect		Subcutaneous	100.0 Milligram			Product used for unknown indication, Asthma

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Back injury	v.24.1	
Back pain	v.24.1	
Drug ineffective	v.24.1	
Dyspnoea exertional	v.24.1	
Fall	v.24.1	
Gait disturbance	v.24.1	
Lumbar vertebral fracture	v.24.1	
Pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04172538	1	2021-05-19	2021-06-01	MAH	2021535400	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
INSULIN HUMAN	Concomitant	NOT SPECIFIED					Type 2 diabetes mellitus
METFORMIN HYDROCHLORIDE/SAXAGLIPTIN HYDROCHLORIDE	Concomitant						Type 2 diabetes mellitus
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain upper	v.24.1	
Back pain	v.24.1	
Fatigue	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Insomnia	v.24.1	
Musculoskeletal chest pain	v.24.1	
Pericarditis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04172552	0	2021-05-19	2021-05-19	MAH	2021545906	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
44 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
SYNTHROID	Concomitant	NOT SPECIFIED					
VITAMIN D [COLECALCIFEROL]	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.24.1	
Flushing	v.24.1	
Hyperhidrosis	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypotension	v.24.1	
Loss of consciousness	v.24.1	
Photosensitivity reaction	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04172575	1	2021-05-19	2021-07-15	MAH	2021503555	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
76 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MOMETASONE FUROATE	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
TYLENOL	Concomitant	NOT SPECIFIED					
VITAMIN D	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Disseminated varicella zoster virus infection	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04172909	2	2021-05-19	2021-08-04	MAH	2021508171	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
79 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETYLSALICYLIC ACID	Concomitant						
HYDROXYCHLOROQUINE	Concomitant						
PENTOXIFYLLINE	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cerebrovascular accident	v.24.1	
Transient ischaemic attack	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04172916	1	2021-05-19	2021-06-01	MAH	2021545731	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
41 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
VENTOLINE [SALBUTAMOL]	Concomitant		Oral		As required		Asthma

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04173687	0	2021-05-19	2021-05-19	MAH	2021SA156059	Study	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
54 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ATARAX [HYDROXYZINE]	Concomitant		Unknown				
BETADERM	Concomitant	NOT SPECIFIED	Unknown				
CETIRIZINE HYDROCHLORIDE	Concomitant		Unknown				
COVID-19 VACCINE	Suspect		Unknown				COVID-19 immunisation
DUPILUMAB	Suspect	Solution for injection	Subcutaneous	300.0 Milligram	1 every 2 Weeks	131.0	Dermatitis atopic
DUPILUMAB	Suspect		Subcutaneous	600.0 Milligram	Total	1.0 Days	Dermatitis atopic
TACROLIMUS	Concomitant	Capsules	Unknown				
VENTOLIN [SALBUTAMOL]	Concomitant		Unknown				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.24.1	1 Months
Fatigue	v.24.1	1 Months
Hyperhidrosis	v.24.1	1 Months
Incorrect dose administered	v.24.1	1 Months
Loss of consciousness	v.24.1	1 Days
Scratch	v.24.1	1 Months

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04173788	1	2021-05-19	2021-09-13	MAH	2021A430050	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
62 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.24.1	1 Days
Muscle rigidity	v.24.1	1 Days
Nausea	v.24.1	1 Days
Pain	v.24.1	1 Days
Tremor	v.24.1	1 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04174407	1	2021-05-19	2021-06-30	MAH	2021382017	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
48 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Burning sensation	v.24.1	
Chills	v.24.1	
Decreased appetite	v.24.1	
Diarrhoea	v.24.1	
Dizziness	v.24.1	
Fatigue	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Feeling abnormal	v.24.1	
Fibrin D dimer increased	v.24.1	
Hyperaesthesia teeth	v.24.1	
Insomnia	v.24.1	30 Days
Malaise	v.24.1	
Muscular weakness	v.24.1	
Nausea	v.24.1	
Pain in extremity	v.24.1	
Paraesthesia	v.24.1	
Poor quality sleep	v.24.1	
Pyrexia	v.24.1	
Sleep disorder	v.24.1	
Tachycardia	v.24.1	
Tinnitus	v.24.1	
Tongue discomfort	v.24.1	
Vaccination site erythema	v.24.1	
Vaccination site induration	v.24.1	
Vaccination site pain	v.24.1	
Vaccination site warmth	v.24.1	
Weight decreased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04174608	1	2021-05-19	2021-05-20	MAH	2021535431	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
77 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETYLSALICYLIC ACID	Concomitant	NOT SPECIFIED	Oral				Prophylaxis
AZOPT	Concomitant	SUSPENSION OPHTHALMIC	Intraocular				Ocular hypertension
CANDESARTAN	Concomitant		Oral				Hypertension
DEXILANT	Concomitant	CAPSULE, DELAYED RELEASE	Oral				Gastrooesophageal reflux disease
LUMIGAN NOS	Concomitant	SOLUTION OPHTHALMIC	Intraocular				Ocular hypertension
METOPROLOL	Concomitant		Oral				Myocardial infarction, Hypertension

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
SIMVASTATIN	Concomitant	Tablets	Oral				Hypercholesterolaemia
SYNTHROID	Concomitant	NOT SPECIFIED	Oral				Hypothyroidism

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthritis	v.24.1	21 Days
Headache	v.24.1	21 Days
Hypoaesthesia	v.24.1	21 Days
Myalgia	v.24.1	21 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04174647	0	2021-05-19	2021-05-19	MAH	2021536157	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Myocardial infarction	v.24.1	
Pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04174870	1	2021-05-19	2021-06-02	MAH	2021541053	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
67 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Deep vein thrombosis	v.24.1	
Peripheral swelling	v.24.1	
Thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04179762	0	2021-05-20	2021-05-20	MAH	2021488177	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
33 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ETHINYL ESTRADIOL/NORETHINDRONE ACETATE	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown			1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dysmenorrhoea	v.24.1	
Malaise	v.24.1	
Menstruation irregular	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Mobility decreased	v.24.1	
Muscular weakness	v.24.1	
Pain in extremity	v.24.1	
Premenstrual pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04179777	0	2021-05-20	2021-05-20	MAH	2021503466	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
25 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bradyphrenia	v.24.1	
Chest pain	v.24.1	
Chills	v.24.1	
Costochondritis	v.24.1	
Dizziness	v.24.1	
Dyspnoea	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Feeling abnormal	v.24.1	
Headache	v.24.1	
Pyrexia	v.24.1	
Syncope	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04180025	1	2021-05-20	2021-07-13	MAH	2021513682	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
61 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ALLOPURINOL	Concomitant	Tablets					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	
Headache	v.24.1	
Herpes zoster	v.24.1	
Rash	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04180802	1	2021-05-20	2021-07-13	MAH	2021541096	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
44 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Lip swelling	v.24.1	2 Days
Sensory loss	v.24.1	
Swelling face	v.24.1	
Venous bruit	v.24.1	1 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04180917	0	2021-05-20	2021-05-20	MAH	2021545921	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown				COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.24.1	3 Days
Pyrexia	v.24.1	3 Days
Vomiting	v.24.1	3 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04180963	2	2021-05-20	2021-08-06	MAH	2021513850	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
38 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ETHINYL ESTRADIOL/LEVONORGESTREL	Concomitant		Oral		1 every 1 Days		Prophylaxis
FLUOXETINE	Concomitant	NOT SPECIFIED	Oral	40.0 Milligram	1 every 1 Days		Depression, Anxiety
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bell's palsy	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Disease recurrence	v.24.1	
Facial pain	v.24.1	
Hypoaesthesia	v.24.1	
Speech disorder	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04182053	1	2021-05-20	2021-07-09	MAH	2021536047	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
64 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
ROSUVASTATIN	Concomitant	NOT SPECIFIED	Oral				Hypercholesterolaemia
SYNTHROID	Concomitant	NOT SPECIFIED	Oral	75.0 Microgram			Hypothyroidism
VITAMIN D	Concomitant	NOT SPECIFIED	Oral				Supplementation therapy

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Diarrhoea	v.24.1	687 Hours
Dizziness	v.24.1	1955 Minutes
Feeling abnormal	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Feeling jittery	v.24.1	1955 Minutes
Flushing	v.24.1	687 Hours
Nausea	v.24.1	2 Days
Nervousness	v.24.1	2 Days
Psychomotor hyperactivity	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04182100	2	2021-05-20	2021-07-07	MAH	2021557242	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
37 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MYCOPHENOLATE MOFETIL	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
RITUXIMAB	Concomitant		Intravenous (not otherwise specified)	1000.0 Milligram			Systemic lupus erythematosus

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Discomfort	v.24.1	
Rash	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04185245	0	2021-05-21	2021-05-21	MAH	CA2021AMR096416	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
61 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				Prophylaxis
VALTREX	Concomitant		Oral	2.0 Dosage forms	3 every 1 Days		Product used for unknown indication
ZEJULA	Suspect	Capsules	Unknown				Ovarian epithelial cancer, Malignant peritoneal neoplasm, Fallopian tube cancer

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ZEJULA	Suspect	Capsules	Unknown				Ovarian epithelial cancer, Malignant peritoneal neoplasm, Fallopian tube cancer
ZEJULA	Suspect	Capsules	Oral	300.0 Milligram	1 every 1 Days		Ovarian epithelial cancer, Malignant peritoneal neoplasm, Fallopian tube cancer
ZOPICLONE	Concomitant	Tablets	Unknown				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal distension	v.24.1	
Constipation	v.24.1	
Dizziness	v.24.1	
Fatigue	v.24.1	
Hospitalisation	v.24.1	
Hyperhidrosis	v.24.1	
Muscle spasms	v.24.1	
Muscle twitching	v.24.1	
Nausea	v.24.1	
Retching	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04185528	4	2021-05-21	2021-09-08	MAH	CA2021AMR104415	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
29 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_03130271
Linked	E2B_04747811
Linked	E2B_04747811
Linked	E2B_03130271
Linked	
Linked	
Linked	E2B_03130271
Linked	
Linked	
Linked	E2B_03130271
Linked	
Linked	E2B_03130271

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				Product used for unknown indication, COVID-19 prophylaxis
COVID-19 VACCINE	Suspect		Unknown				Product used for unknown indication, COVID-19 prophylaxis
MEPOLIZUMAB	Suspect		Subcutaneous	100.0 Milligram			Product used for unknown indication, Asthma
MEPOLIZUMAB	Suspect	Powder for injection	Subcutaneous	100.0 Milligram			Product used for unknown indication, Asthma
MEPOLIZUMAB	Suspect	Powder for injection	Subcutaneous	100.0 Milligram			Product used for unknown indication, Asthma
REACTINE	Suspect	NOT SPECIFIED	Unknown		1 every 1 Days		Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain	v.24.1	
Anxiety	v.24.1	
Arrhythmia	v.24.1	
Breath sounds abnormal	v.24.1	
Depression	v.24.1	
Discomfort	v.24.1	
Dry eye	v.24.1	
Dry skin	v.24.1	
Eye pruritus	v.24.1	
Fatigue	v.24.1	
Hypersensitivity	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Injection site pain	v.24.1	
Insomnia	v.24.1	
Lacrimation increased	v.24.1	
Muscular weakness	v.24.1	
Nasal congestion	v.24.1	
Nephrolithiasis	v.24.1	
Ocular hyperaemia	v.24.1	
Oropharyngeal pain	v.24.1	
Pyrexia	v.24.1	
Rash	v.24.1	
Rash erythematous	v.24.1	
Seasonal allergy	v.24.1	
Sinus congestion	v.24.1	
Skin irritation	v.24.1	
Sleep apnoea syndrome	v.24.1	
Sleep disorder	v.24.1	
Weight decreased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04185836	0	2021-05-21	2021-05-21	MAH	20210522748	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
68 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AMLODIPINE BESILATE	Concomitant			5.0 Milligram			Hypertension
COVID-19 VACCINE	Suspect		Unknown				Immunisation
DEXLANSOPRAZOLE	Concomitant			60.0 Milligram			Antacid therapy
REMICADE	Suspect	POWDER FOR SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)				Crohn's disease

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Diarrhoea	v.24.1	
Drug interaction	v.24.1	
Oral herpes	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04187923	0	2021-05-21	2021-05-21	MAH	2021548074	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
55 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ATACAND	Concomitant	Tablets					
BUDESONIDE/FORMOTEROL FUMARATE	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
SYNTHROID	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	5 Days
Headache	v.24.1	5 Days

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Nausea	v.24.1	
Pain in extremity	v.24.1	5 Days
Vertigo	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04187934	1	2021-05-21	2021-07-13	MAH	2021548069	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
46 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	10 Days
Cough	v.24.1	
Fatigue	v.24.1	10 Days
Illness	v.24.1	
Pulmonary congestion	v.24.1	
Vaccination site pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04188204	1	2021-05-21	2021-06-25	MAH	2021529365	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
68 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
NITROGLYCERIN	Concomitant		Sublingual				Cardiovascular disorder
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Allergy to vaccine	v.24.1	
Balance disorder	v.24.1	
Chest pain	v.24.1	1 Months
Erythema	v.24.1	1 Months

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Feeling abnormal	v.24.1	
Lip swelling	v.24.1	1 Months
Myalgia	v.24.1	1 Months
Pain	v.24.1	
Pain in extremity	v.24.1	1 Months
Pruritus	v.24.1	1 Months
Rash	v.24.1	
Urticaria	v.24.1	1 Months

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04188221	0	2021-05-21	2021-05-21	MAH	2021517180	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
35 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abnormal sensation in eye	v.24.1	
Chills	v.24.1	
Eye pain	v.24.1	
Fatigue	v.24.1	
Pyrexia	v.24.1	
Swelling face	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04188317	1	2021-05-21	2021-06-17	MAH	2021517217	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
52 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
DESVENLAFAXINE SUCCINATE	Concomitant			50.0 Milligram			
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
SEMAGLUTIDE	Concomitant	SOLUTION SUBCUTANEOUS		1.0 Milligram			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.24.1	
Confusional state	v.24.1	
Dizziness	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dysphagia	v.24.1	
Ear pruritus	v.24.1	
Erythema	v.24.1	
Eye swelling	v.24.1	
Heart rate increased	v.24.1	
Mouth swelling	v.24.1	
Panic reaction	v.24.1	
Paraesthesia	v.24.1	
Paraesthesia oral	v.24.1	
Swelling face	v.24.1	
Throat irritation	v.24.1	
Throat tightness	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04188362	0	2021-05-21	2021-05-21	MAH	2021548120	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
25 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Diarrhoea	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04188402	0	2021-05-21	2021-05-21	MAH	2021515875	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
29 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
GRAVOL	Concomitant	NOT SPECIFIED					
IBUPROFEN	Concomitant						
NEXIUM [ESOMEPRAZOLE MAGNESIUM]	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown			1.0 Days	COVID-19 immunisation
TYLENOL	Concomitant	NOT SPECIFIED					
VISANNE	Concomitant	Tablets					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Back pain	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Breast pain	v.24.1	
Dizziness	v.24.1	
Headache	v.24.1	
Nausea	v.24.1	
Neck pain	v.24.1	
Neurogenic shock	v.24.1	
Pain in extremity	v.24.1	
Photophobia	v.24.1	
Vaccination site pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04188425	0	2021-05-21	2021-05-21	MAH	2021548097	Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
24 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Depressed level of consciousness	v.24.1	15 Minutes
Dizziness	v.24.1	15 Minutes
Feeling hot	v.24.1	15 Minutes
Hypopnoea	v.24.1	15 Minutes
Pallor	v.24.1	15 Minutes
Syncope	v.24.1	15 Minutes

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04188530	0	2021-05-21	2021-05-21	MAH	2021561341	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
57 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Urinary retention	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04188706	1	2021-05-21	2021-07-06	MAH	2021555492	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
37 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CETIRIZINE HYDROCHLORIDE	Concomitant				As required		
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anal incontinence	v.24.1	
Anxiety	v.24.1	
Chest discomfort	v.24.1	
Dizziness	v.24.1	
Eye movement disorder	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hyperhidrosis	v.24.1	
Lip swelling	v.24.1	
Nausea	v.24.1	
Seizure like phenomena	v.24.1	
Tremor	v.24.1	
Urinary incontinence	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04188748	1	2021-05-21	2021-05-25	MAH	2021515597	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
58 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blindness transient	v.24.1	
Dizziness	v.24.1	
Nausea	v.24.1	
Vision blurred	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04188751	1	2021-05-21	2021-07-12	MAH	2021555568	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.24.1	
Drug ineffective	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04190035	1	2021-05-22	2021-06-11	MAH	2569602	Study	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
43 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				Product used for unknown indication
OCRELIZUMAB	Suspect		Intravenous (not otherwise specified)	300.0 Milligram			Relapsing-remitting multiple sclerosis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Dysarthria	v.24.1	
Emotional distress	v.24.1	
Gait inability	v.24.1	
Hemianaesthesia	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pyrexia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04191026	1	2021-05-24	2021-08-18	MAH	CA2021AMR106844	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
72 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	E2B_05231487
Linked	
Linked	E2B_03600551
Linked	E2B_02864124
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	E2B_03600551
Linked	E2B_02864124
Linked	
Linked	
Linked	E2B_04900803
Linked	E2B_05231487
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BUDESONIDE/FORMOTEROL FUMARATE	Concomitant		Unknown				Product used for unknown indication
COVID-19 VACCINE	Suspect		Unknown				Prophylaxis
MEPOLIZUMAB	Suspect	Powder for injection	Subcutaneous	100.0 Milligram			Product used for unknown indication, Asthma
MEPOLIZUMAB	Suspect		Subcutaneous	100.0 Milligram			Product used for unknown indication, Asthma
METFORMIN	Concomitant		Unknown				Product used for unknown indication
MONTELUKAST SODIUM	Concomitant		Unknown				Product used for unknown indication
PANTOPRAZOLE	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication
SPIRIVA	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication
VENTOLIN	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthmatic crisis	v.24.1	
Blood glucose increased	v.24.1	
Dyspnoea exertional	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04191287	2	2021-05-24	2021-07-12	MAH	MOD-2021-116602	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
26 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	1.0 Dosage forms			COVID-19 immunisation
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	Injection					COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	18 Days
Chest pain	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.24.1	
Cognitive disorder	v.24.1	
Confusional state	v.24.1	
Conversion disorder	v.24.1	
Depressed level of consciousness	v.24.1	
Dizziness	v.24.1	5 Days
Dyspnoea	v.24.1	
Feeling abnormal	v.24.1	
Headache	v.24.1	5 Days
Hyperhidrosis	v.24.1	
Hypersensitivity	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Mastication disorder	v.24.1	
Mobility decreased	v.24.1	
Muscle contractions involuntary	v.24.1	
Muscle contractions involuntary	v.24.1	
Muscle spasms	v.24.1	
Muscle twitching	v.24.1	
Muscular weakness	v.24.1	19 Days
Musculoskeletal stiffness	v.24.1	422 Hours
Myalgia	v.24.1	18 Days
Nausea	v.24.1	
Neuropathy peripheral	v.24.1	
Tremor	v.24.1	
Vertigo	v.24.1	5 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04192550	0	2021-05-24	2021-05-24	MAH	2833020	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
76 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BENADRYL	Concomitant	NOT SPECIFIED	Oral	50.0 Milligram			
CALCIUM	Concomitant	NOT SPECIFIED					
COVID-19 VACCINE	Suspect		Unknown			1.0 Days	Product used for unknown indication
DEXILANT	Concomitant	CAPSULE, DELAYED RELEASE					
FOLIC ACID	Concomitant	NOT SPECIFIED					
METFORMIN	Concomitant	Tablet	Unknown				
METHOTREXATE	Concomitant	NOT SPECIFIED	Subcutaneous	7.5 Milligram			Rheumatoid arthritis
PREDNISONE	Concomitant	NOT SPECIFIED	Unknown	10.0 Milligram	1 every 1 Days		Rheumatoid arthritis
RITUXIMAB	Suspect		Intravenous drip	1000.0 Milligram			Rheumatoid arthritis

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ROSUVASTATIN	Concomitant	NOT SPECIFIED	Subcutaneous				
SOLU-MEDROL	Concomitant	NOT SPECIFIED	Intravenous (not otherwise specified)	10.0 Milligram			
TYLENOL	Concomitant	NOT SPECIFIED	Oral	650.0 Milligram			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cellulitis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04194766	0	2021-05-24	2021-05-24	MAH	2021556153	Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
25 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Menstruation irregular	v.24.1	
Pain in extremity	v.24.1	
Pain in extremity	v.24.1	2 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04194825	0	2021-05-24	2021-05-24	MAH	2021555691	Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
28 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COLLAGEN	Concomitant		Oral				Supplementation therapy
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
VITAMIN D3	Concomitant		Oral				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Muscular weakness	v.24.1	
Myalgia	v.24.1	
Pain in extremity	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Vaccination site pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04194872	0	2021-05-24	2021-05-24	MAH	2021523377	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
53 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACITRETIN	Concomitant	NOT SPECIFIED					
NIFEDIPINE XL	Concomitant	TABLET (EXTENDED-RELEASE)					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
VENTOLIN [SALBUTAMOL]	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Rash	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04194882	1	2021-05-24	2021-06-08	MAH	2021523768	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
73 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETYLSALICYLIC ACID	Concomitant		Oral	81.0 Milligram	1 every 1 Days		Hypercholesterolaemia
ATORVASTATIN	Concomitant		Oral	20.0 Milligram	1 every 1 Days		Hypercholesterolaemia
EZETROL	Concomitant	Tablets	Oral	10.0 Milligram	1 every 1 Days		Hypercholesterolaemia
OMEPRAZOLE	Concomitant	NOT SPECIFIED	Oral	20.0 Milligram	1 every 1 Days		Prophylaxis
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
RAMIPRIL	Concomitant	NOT SPECIFIED	Oral	5.0 Milligram	1 every 1 Days		Hypertension

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain lower	v.24.1	5130 Minutes
Peripheral artery thrombosis	v.24.1	4 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04194976	0	2021-05-24	2021-05-24	MAH	2021523948	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
92 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dyskinesia	v.24.1	
Hallucination	v.24.1	
Hypoaesthesia	v.24.1	
Paraesthesia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04194980	1	2021-05-24	2021-06-01	MAH	2021524338	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
66 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bell's palsy	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04198262	1	2021-05-25	2021-06-09	MAH	2021560567	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
38 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	
Muscle spasms	v.24.1	
Pain in extremity	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04198332	1	2021-05-25	2021-06-08	MAH	2021559814	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
62 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CIPRALEX [ESCITALOPRAM]	Concomitant		Oral				Anxiety
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pain in extremity	v.24.1	
Paraesthesia	v.24.1	-106
Thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04198595	0	2021-05-25	2021-05-25	MAH	2021570371	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
28 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Months	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Multiple organ dysfunction syndrome	v.24.1	
Renal failure	v.24.1	
Thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04198712	2	2021-05-25	2021-07-06	MAH	2021560483	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
60 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BUDESONIDE/FORMOTEROL FUMARATE	Concomitant						Asthma
PANTOLOC [PANTOPRAZOLE]	Concomitant						Gastrooesophageal reflux disease
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
SPIRIVA	Concomitant	NOT SPECIFIED	Intra-nasal				Asthma
VENTOLINE [SALBUTAMOL]	Concomitant						Asthma

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Erythema	v.24.1	
Feeling hot	v.24.1	
Pain in extremity	v.24.1	
Peripheral swelling	v.24.1	
Phlebitis superficial	v.24.1	
Thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04198744	0	2021-05-25	2021-05-25	MAH	2021568109	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
40 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ATIVAN	Concomitant	NOT SPECIFIED	Oral				Depression, Anxiety
ELTROXIN	Concomitant	Tablets	Oral				Depression, Anxiety
GABAPENTIN	Concomitant	NOT SPECIFIED	Oral				Depression, Anxiety
NEXIUM [ESOMEPRAZOLE MAGNESIUM]	Concomitant		Oral				Gastrooesophageal reflux disease
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PROPRANOLOL	Concomitant	NOT SPECIFIED	Oral				Depression, Anxiety
VENLAFAXINE	Concomitant		Oral				Depression

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anxiety	v.24.1	
Depressed mood	v.24.1	
Fatigue	v.24.1	
Frustration tolerance decreased	v.24.1	
Neck mass	v.24.1	
Pain in extremity	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04200223	0	2021-05-25	2021-05-25	MAH	2021560154	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
47 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ARNICA MONTANA	Concomitant						
CALCIUM	Concomitant	NOT SPECIFIED			As required		
CANNABIDIOL	Concomitant				As required		
COPAXONE	Concomitant			20.0 Milligram	every 1 Days		Multiple sclerosis
GLUTATHIONE	Concomitant	NOT SPECIFIED					
L-GLUTAMINE [GLUTAMIC ACID]	Concomitant						
NALTREXONE	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
TRANEXAMIC ACID	Concomitant	NOT SPECIFIED					
VITAMIN C [ASCORBIC ACID]	Concomitant						
VITAMIN D	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Haemorrhage	v.24.1	
Mental disorder	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04200398	0	2021-05-25	2021-05-25	MAH	2021541500	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Illness	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04201614	1	2021-05-25	2021-05-25	MAH	2021-CA-1913491	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
32 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COPAXONE	Suspect		Unknown		3 every 1 Weeks		Multiple sclerosis
ERGOCALCIFEROL	Concomitant						
FOLIC ACID/IRON/MINERALS NOS/VITAMINS NOS	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dyspepsia	v.24.1	
Fatigue	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Flushing	v.24.1	
Injection site haemorrhage	v.24.1	
Injection site swelling	v.24.1	
Myalgia	v.24.1	
Pain	v.24.1	
Throat tightness	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04202217	0	2021-05-25	2021-05-25	MAH	21K-028-3910397-00	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
76 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ARAVA	Suspect	Tablets	Unknown				Rheumatoid arthritis
COVID-19 VACCINE	Suspect		Intramuscular			1.0 Days	COVID-19 immunisation
HUMIRA	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous				Rheumatoid arthritis
METHOTREXATE	Suspect	NOT SPECIFIED	Subcutaneous				Rheumatoid arthritis
METHYLPREDNISOLONE ACETATE	Concomitant						Rheumatoid arthritis
PLAQUENIL	Concomitant	Tablets					Rheumatoid arthritis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Arthritis	v.24.1	
Drug ineffective	v.24.1	
Drug ineffective	v.24.1	
Emotional distress	v.24.1	
Joint stiffness	v.24.1	
Malaise	v.24.1	
Peripheral swelling	v.24.1	
Therapeutic product effect incomplete	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04202264	1	2021-05-25	2021-07-13	MAH	2021530364	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
74 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CLOPIDOGREL BISULFATE	Concomitant						

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COBALTOUS SULFATE/COPPER SULFATE/CYANOCOBALAMIN/D-ALPHA TOCOPHEROL/ERGOCALCIFEROL/FERROUS FUMARATE/MAGNESIUM SULFATE/MANGANESE SULFATE/NICOTINAMIDE/POTASSIUM IODIDE/PYRIDOXINE HYDROCHLORIDE/RIBOFLAVIN/THIAMINE HYDROCHLORIDE/VITAMIN A/VITAMIN C	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
RABEPRAZOLE	Concomitant						
ROSUVASTATIN CALCIUM	Concomitant						
TEVA-DULOXETINE	Concomitant	NOT SPECIFIED	Unknown				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Balance disorder	v.24.1	
Deafness unilateral	v.24.1	
Fatigue	v.24.1	
Headache	v.24.1	
Nausea	v.24.1	
Vertigo	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04202308	1	2021-05-25	2021-07-08	MAH	2021530860	Spontaneous	Consumer/other non health professional

Serious report?
Serious

Death:	No	**Disability:**	No	**Congenital Anomaly:**	No
Life Threatening:	No	**Hospitalization:**	No	**Other Medically Important Conditions:**	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
45 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CELEBREX	Concomitant	Capsules					
CYCLOBENZAPRINE	Concomitant						
FOQUEST	Concomitant	NOT SPECIFIED					
IRON	Concomitant						
LATUDA FILM-COATED TABLETS	Concomitant	Tablets					
LYRICA	Concomitant	Capsules					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Heart rate increased	v.24.1	
Hypertension	v.24.1	-119
Pain in extremity	v.24.1	
Skin discolouration	v.24.1	
Thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04207609	2	2021-05-26	2021-08-13	MAH	2021A455781	Published	Physician

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
63 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_04321224

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Aortic thrombosis	v.24.1	
Immune thrombocytopenia	v.24.1	
Peripheral artery occlusion	v.24.1	
Peripheral ischaemia	v.24.1	
Pulmonary artery thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04207668	0	2021-05-26	2021-05-26	MAH	2832866	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
86 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	E2B_03889255
Linked	E2B_04432930
Linked	E2B_05011683
Linked	E2B_03889255
Linked	E2B_05011683
Linked	E2B_04432930
Linked	E2B_03889255
Linked	E2B_03889255
Linked	E2B_03889255

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACTEMRA	Suspect	NOT SPECIFIED	Subcutaneous	162.0 Milligram	1 every 1 Weeks	1.0 Years	Vasculitis, Giant cell arteritis
ACTEMRA	Suspect	Solution for injection in pre-filled syringe	Subcutaneous	162.0 Milligram		1.0 Days	Vasculitis, Giant cell arteritis

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACTEMRA	Suspect	Solution for injection in pre-filled syringe	Subcutaneous	162.0 Milligram	1 every 1 Weeks		Vasculitis, Giant cell arteritis
ACTEMRA	Suspect	Solution for injection in pre-filled syringe	Subcutaneous	162.0 Milligram	1 every 2 Weeks	1.0 Days	Vasculitis, Giant cell arteritis
ALENDRONATE SODIUM	Concomitant						
CALCIUM LACTATE	Concomitant	Tablet					
CLOBETASOL	Concomitant	Cream					Aphthous ulcer
CLOZAPINE	Concomitant	Tablets					
COVID-19 VACCINE	Suspect		Unknown				Product used for unknown indication
GLYBURIDE	Concomitant	Tablets					
INSULIN	Concomitant	GLOBULES ORAL					
METFORMIN	Concomitant	Tablet	Unknown				
PANTOLOC	Concomitant	TABLET (ENTERIC-COATED)					
PLANTAGO OVATA	Concomitant						Diarrhoea
PREDNISONE	Concomitant	NOT SPECIFIED					
VALACYCLOVIR	Concomitant	NOT SPECIFIED					
XARELTO	Concomitant	Coated tablet					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Dizziness	v.24.1	
Nausea	v.24.1	
Pain in extremity	v.24.1	
Syncope	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04207823	2	2021-05-26	2021-06-24	MAH	MOD-2021-132350	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
52 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	1.0 Dosage forms			COVID-19 immunisation
SIMPONI	Concomitant	SOLUTION SUBCUTANEOUS	Unknown	1.0 Dosage forms			Arthritis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Contusion	v.24.1	
Haemorrhage subcutaneous	v.24.1	
Pruritus	v.24.1	
Skin reaction	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04208288	1	2021-05-26	2021-07-12	MAH	2021583382	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
35 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown			1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Vaginal haemorrhage	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04208305	0	2021-05-26	2021-05-26	MAH	2021536231	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
73 Years	Male		73 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Tinnitus	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04208313	0	2021-05-26	2021-05-26	MAH	2021569166	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
19 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Haemoglobin decreased	v.24.1	
Heavy menstrual bleeding	v.24.1	
Menstrual disorder	v.24.1	
Platelet count decreased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04208863	1	2021-05-26	2021-07-15	MAH	2021535496	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
28 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ALIGN	Concomitant						
COLESTID	Concomitant	NOT SPECIFIED					
DESOGESTREL/ETHINYL ESTRADIOL	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
SERTRALINE HYDROCHLORIDE	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pulmonary embolism	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04208941	1	2021-05-26	2021-06-04	MAH	2021568963	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
55 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dry skin	v.24.1	
Eye pruritus	v.24.1	5 Minutes
Fluid retention	v.24.1	
Headache	v.24.1	
Hypersensitivity	v.24.1	
Hypotension	v.24.1	-130

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Malaise	v.24.1	
Periorbital swelling	v.24.1	48 Hours
Skin tightness	v.24.1	
Swelling face	v.24.1	48 Hours

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04209041	2	2021-05-26	2021-08-20	MAH	2021534745	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
81 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cerebrovascular accident	v.24.1	
Hemiparesis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04209072	1	2021-05-26	2021-06-09	MAH	2021534379	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
53 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ANGELIQ	Concomitant	Tablets					Hormone therapy
ARAVA	Concomitant	Tablets					Asthma
BACLOFEN	Concomitant	NOT SPECIFIED					Muscle spasms
BUDESONIDE/FORMOTEROL FUMARATE	Concomitant						Asthma
GABAPENTIN	Concomitant	NOT SPECIFIED					Neuralgia
MINOCYCLINE	Concomitant	NOT SPECIFIED					Multiple sclerosis
MODAFINIL	Concomitant	NOT SPECIFIED					Somnolence
MYRBETRIQ	Concomitant	TABLET (EXTENDED-RELEASE)					Bladder disorder

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PANTOLOC [PANTOPRAZOLE]	Concomitant						Abdominal discomfort
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
PREMARIN	Concomitant	NOT SPECIFIED					Hormone therapy

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.24.1	1 Days
Dyspnoea	v.24.1	
Fatigue	v.24.1	2 Days
Headache	v.24.1	2 Days
Pain in extremity	v.24.1	2 Days
Postmenopausal haemorrhage	v.24.1	136 Hours

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04209088	0	2021-05-26	2021-05-26	MAH	2021534789	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
54 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.24.1	
Diarrhoea	v.24.1	
Fatigue	v.24.1	
Pyrexia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04209219	0	2021-05-26	2021-05-26	MAH	2021568977	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
7 Decade	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Contusion	v.24.1	
Pain in extremity	v.24.1	
Thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04209309	1	2021-05-26	2021-07-08	MAH	2021583421	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
42 Years	Female			Recovered/resolved with sequelae

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arrhythmia	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Off label use	v.24.1	
Tachycardia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04213201	0	2021-05-27	2021-05-27	MAH	2021559117	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.24.1	
Drug ineffective	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04213210	0	2021-05-27	2021-05-27	MAH	2021559118	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.24.1	
Drug ineffective	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04213214	0	2021-05-27	2021-05-27	MAH	2021559092	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.24.1	
Drug ineffective	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04213805	2	2021-05-27	2021-07-13	MAH	2021546215	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
27 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ALMOTRIPTAN	Concomitant	Tablets					
AMITRIPTYLINE	Concomitant						
CANNABIDIOL	Concomitant						
MEDROXYPROGESTERONE ACETATE	Concomitant		Intramuscular		1 every 1 Months		Contraception
METOLAZONE	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown	0.3 ml	Total	1.0 Days	COVID-19 immunisation
VENLAFAXINE HYDROCHLORIDE	Concomitant		Oral	150.0 Milligram	every 1 Days		Anxiety

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
VYVANSE	Concomitant	Capsules	Oral	20.0 Milligram	every 1 Days		Attention deficit hyperactivity disorder

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Blood pressure decreased	v.24.1	
Burning sensation	v.24.1	
Diarrhoea	v.24.1	
Dizziness	v.24.1	
Hyperhidrosis	v.24.1	
Micturition urgency	v.24.1	
Movement disorder	v.24.1	
Nausea	v.24.1	
Pain in extremity	v.24.1	
Pallor	v.24.1	
Shock	v.24.1	
Speech disorder	v.24.1	
Syncope	v.24.1	
Thirst	v.24.1	
Visual acuity reduced	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04213858	1	2021-05-27	2021-09-09	MAH	2021541647	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
47 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.24.1	
Drug ineffective	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04214775	2	2021-05-27	2021-07-15	MAH	2021542051	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
40 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
GABAPENTIN	Concomitant	NOT SPECIFIED					
LEVOTHYROXINE SODIUM	Concomitant	NOT SPECIFIED	Unknown				
MAGNESIUM BIS GLYCINATE	Concomitant						
MELATONIN	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
VENLAFAXINE HYDROCHLORIDE	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Muscle spasms	v.24.1	0 Days
Nausea	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04215588	2	2021-05-27	2021-07-23	MAH	2021541511	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
62 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVERSYL PLUS HD	Concomitant	Tablets					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Joint swelling	v.24.1	
Musculoskeletal pain	v.24.1	
Pain in extremity	v.24.1	
Peripheral swelling	v.24.1	
Vaccination site erythema	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Vaccination site swelling	v.24.1	
Vaccination site warmth	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04215596	0	2021-05-27	2021-05-27	MAH	2021583750	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
28 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown			1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bedridden	v.24.1	5 Days
Dizziness	v.24.1	
Fatigue	v.24.1	
Head discomfort	v.24.1	
Headache	v.24.1	
Impaired quality of life	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Malaise	v.24.1	
Palpitations	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04215629	1	2021-05-27	2021-08-03	MAH	2021542686	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
47 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
HUMIRA	Concomitant	SOLUTION SUBCUTANEOUS	Subcutaneous				Crohn's disease
METRONIDAZOLE	Concomitant	NOT SPECIFIED	Oral				Vaginal infection
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Menstrual disorder	v.24.1	
Pain in extremity	v.24.1	
Vaginal haemorrhage	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04215767	13	2021-05-27	2021-12-30	MAH	2021BI01004720	Study	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Duplicate	E2B_04652977

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE	Suspect		Unknown				COVID-19 prophylaxis
TYSABRI	Suspect	Unknown	Intravenous (not otherwise specified)	300.0 Milligram	1 every 4 Weeks		Multiple sclerosis
TYSABRI	Suspect	Unknown	Intravenous (not otherwise specified)	300.0 Milligram	1 every 4 Weeks		Multiple sclerosis
TYSABRI	Suspect	Unknown	Intravenous (not otherwise specified)	300.0 Milligram	1 every 4 Weeks		Multiple sclerosis
TYSABRI	Suspect	Unknown	Intravenous (not otherwise specified)				Multiple sclerosis

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
TYSABRI	Suspect	Unknown	Intravenous (not otherwise specified)	300.0 Milligram	1 every 4 Weeks		Multiple sclerosis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain	v.24.1	
Abdominal rigidity	v.24.1	
Anxiety	v.24.1	
Asthenia	v.24.1	
Balance disorder	v.24.1	
Bone contusion	v.24.1	
Burning sensation	v.24.1	
Chills	v.24.1	1 Days
Choking	v.24.1	
Confusional state	v.24.1	
Contusion	v.24.1	
Cystitis	v.24.1	
Diarrhoea	v.24.1	
Emotional distress	v.24.1	
Eye injury	v.24.1	
Eye pain	v.24.1	
Fall	v.24.1	
Fatigue	v.24.1	
Gait disturbance	v.24.1	
Gastrointestinal disorder	v.24.1	
Haematochezia	v.24.1	
Haemorrhage	v.24.1	
Hand deformity	v.24.1	
Head injury	v.24.1	
Irritable bowel syndrome	v.24.1	
Joint swelling	v.24.1	
Mass	v.24.1	
Mobility decreased	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Muscle spasms	v.24.1	
Muscle twitching	v.24.1	
Musculoskeletal disorder	v.24.1	
Neck mass	v.24.1	
Ocular hyperaemia	v.24.1	
Oropharyngeal pain	v.24.1	
Pain	v.24.1	
Pharyngeal hypoaesthesia	v.24.1	
Sleep apnoea syndrome	v.24.1	
Speech disorder	v.24.1	
Spinal column injury	v.24.1	
Swollen tongue	v.24.1	
Syncope	v.24.1	
Tongue movement disturbance	v.24.1	
Tremor	v.24.1	
Urinary tract infection	v.24.1	
Vascular rupture	v.24.1	
Vision blurred	v.24.1	
Visual impairment	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04219693	1	2021-05-28	2021-07-15	MAH	2021547284	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
29 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Heavy menstrual bleeding	v.24.1	
Muscle spasms	v.24.1	
Thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04219701	1	2021-05-28	2021-07-14	MAH	2021583752	Spontaneous	Consumer/other non health professional

Serious report?
Serious

Death:	No	**Disability:**	No	**Congenital Anomaly:**	No
Life Threatening:	No	**Hospitalization:**	No	**Other Medically Important Conditions:**	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
59 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
NAPROXEN	Concomitant	NOT SPECIFIED					
OMEGA 3 [FISH OIL]	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
SYNTHROID	Concomitant	NOT SPECIFIED					
TURMERIC [CURCUMA LONGA]	Concomitant						
VITAMIN D3	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Feeling abnormal	v.24.1	
Hypoacusis	v.24.1	
Hypoaesthesia	v.24.1	
Nausea	v.24.1	
Pyrexia	v.24.1	
Tinnitus	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04219806	0	2021-05-28	2021-05-28	MAH	2021581796	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
64 Years	Male		54 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETAMINOPHEN	Concomitant						
CIMETIDINE	Concomitant	NOT SPECIFIED					
COLESTID	Concomitant	NOT SPECIFIED					
CYANOCOBALAMIN	Concomitant						
DEXAMETHASONE	Concomitant	NOT SPECIFIED					
DIPHENHYDRAMINE	Concomitant						
FISH OIL 600 EPA/300 DHA	Concomitant	Capsule					
MULTIVITAMINS [ASCORBIC ACID;ERGOCALCIFEROL;FOLIC ACID;NICOTINAMIDE;PA	Concomitant						

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PATISIRAN SODIUM	Suspect		Intravenous (not otherwise specified)	0.3 mg/kg			Polyneuropathy
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Months	COVID-19 immunisation
VITAMIN B COMPLEX	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Amyloidosis	v.24.1	
Asthenia	v.24.1	
Condition aggravated	v.24.1	
Discomfort	v.24.1	
Dizziness	v.24.1	
Dyspnoea	v.24.1	
Fatigue	v.24.1	
Head discomfort	v.24.1	-99
Heart rate decreased	v.24.1	
Hypotension	v.24.1	-99
Incoherent	v.24.1	
Malaise	v.24.1	
Somnolence	v.24.1	
Urinary tract infection	v.24.1	
Weight decreased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04219857	1	2021-05-28	2021-07-13	MAH	2021548213	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
56 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.24.1	
Malaise	v.24.1	
Vertigo	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04220040	0	2021-05-28	2021-05-28	MAH	2021A402780	Spontaneous	Consumer/other non health professional

Serious report?
Serious

Death:	Yes	**Disability:**	No	**Congenital Anomaly:**	No
Life Threatening:	No	**Hospitalization:**	Yes	**Other Medically Important Conditions:**	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Fatal

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.5 ml			Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Thrombocytopenia	v.24.1	
Thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04220054	1	2021-05-28	2021-08-10	MAH	2021583622	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
28 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Ophthalmic herpes zoster	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04220312	1	2021-05-28	2021-06-09	MAH	2021549682	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
38 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
LEVOXINE [LEVOFLOXACIN HEMIHYDRATE]	Concomitant		Oral				Multiple sclerosis
MORPHINE	Concomitant	NOT SPECIFIED	Oral				Multiple sclerosis
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
PREGABALIN	Concomitant	Capsules	Oral				Multiple sclerosis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	
Gait disturbance	v.24.1	
Multiple sclerosis	v.24.1	
Sensory disturbance	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04220522	1	2021-05-28	2021-08-25	MAH	2021547940	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04222221	1	2021-05-28	2021-08-28	MAH	2837666	Study	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
48 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				Product used for unknown indication
OCRELIZUMAB	Suspect		Intravenous (not otherwise specified)	300.0 Milligram	1 every 2 Weeks		Relapsing-remitting multiple sclerosis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Decreased appetite	v.24.1	
Dizziness	v.24.1	
Dysstasia	v.24.1	
Hypoaesthesia	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypoxia	v.24.1	
Loss of personal independence in daily activities	v.24.1	
Nausea	v.24.1	
Palpitations	v.24.1	
Somnolence	v.24.1	
Vertigo	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information

***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04222407	0	2021-05-29	2021-05-29	MAH	21K-028-3783429-00	Study	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
65 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular			0.0	COVID-19 immunisation
HUMIRA	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous	40.0 Milligram	1 every 2 Weeks		Crohn's disease
HUMIRA	Suspect	Solution for injection in pre-filled pen	Subcutaneous	80.0 Milligram	1 every 1 Weeks		Crohn's disease

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Crohn's disease	v.24.1	0
Drug ineffective	v.24.1	
Drug level abnormal	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Faecal calprotectin increased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04222698	0	2021-05-29	2021-05-29	MAH	2021584957	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
DEXILANT	Concomitant	CAPSULE, DELAYED RELEASE					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
THYROID	Concomitant						
TRAZODONE	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain	v.24.1	
Diarrhoea	v.24.1	3 Days

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.24.1	1 Weeks
Migraine	v.24.1	1 Days
Vomiting	v.24.1	1 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04222711	0	2021-05-29	2021-05-29	MAH	2021548386	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
52 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AMLODIPINE	Concomitant	Tablets					
COLA ACUMINATA	Concomitant	GLOBULES ORAL					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
RUPATADINE	Concomitant						
SINGULAIR	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Angioedema	v.24.1	
Urticaria	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04223652	0	2021-05-30	2021-05-30	MAH	2021612243	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
33 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	-128
Limb discomfort	v.24.1	-128
Pain	v.24.1	-128
Vaccination site pain	v.24.1	-128

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04226151	1	2021-05-31	2021-06-22	MAH	MOD-2021-162361	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
24 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	1.0 Dosage forms			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Diarrhoea	v.24.1	
Dizziness	v.24.1	
Dizziness	v.24.1	1 Weeks
Dysarthria	v.24.1	
Dyskinesia	v.24.1	
Dyspnoea	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	
Gait inability	v.24.1	
Headache	v.24.1	
Hypoaesthesia	v.24.1	
Hypoaesthesia	v.24.1	
Hypokinesia	v.24.1	
Loss of consciousness	v.24.1	
Nausea	v.24.1	
Palpitations	v.24.1	
Peripheral coldness	v.24.1	
Pyrexia	v.24.1	
Seizure	v.24.1	
Sensory loss	v.24.1	
Somnolence	v.24.1	
Tremor	v.24.1	
Vaccination site pain	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04228293	2	2021-05-31	2021-08-12	MAH	2020TUS054045	Study	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
61 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				COVID-19 immunisation
CUTAQUIG	Concomitant		Subcutaneous	2.0 Milligram	4 every 1 Weeks		
HUMAN C1 ESTERASE INHIBITOR	Concomitant		Intravenous (not otherwise specified)	1500.0 ml			
IMMUNOGLOBULIN (HUMAN)	Suspect		Subcutaneous	8.0 Gram	1 every 1 Weeks		Secondary immunodeficiency
IMMUNOGLOBULIN (HUMAN)	Suspect	Solution for infusion	Subcutaneous	10.0 Gram	1 every 1 Weeks		Secondary immunodeficiency

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Allergy to vaccine	v.24.1	
Anaphylactic reaction	v.24.1	14 Days
Angioedema	v.24.1	14 Days
COVID-19 immunisation	v.24.1	
Hospitalisation	v.24.1	
Medication error	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04229059	1	2021-05-31	2021-07-08	MAH	2021618746	Spontaneous	Physician

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
79 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AMLODIPINE	Concomitant	Tablets					
ASA	Concomitant	NOT SPECIFIED					
ATENOLOL	Concomitant	Tablets					
ATORVASTATIN	Concomitant	Tablets					
CANDESARTAN	Concomitant						
CYANOCOBALAMIN	Concomitant						
GLICLAZIDE	Concomitant	Tablets					
HYDROCHLOROTHIAZIDE	Concomitant	Tablets					
METFORMIN	Concomitant						
OMNARIS	Concomitant	SPRAY, METERED DOSE					
PANTOPRAZOLE	Concomitant	NOT SPECIFIED					

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
TERAZOSIN	Concomitant	Tablets					
TIMOLOL	Concomitant	NOT SPECIFIED					
VITAMIN D3	Concomitant	Capsules					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Conversion disorder	v.24.1	
Encephalitis autoimmune	v.24.1	
Loss of consciousness	v.24.1	
Pyrexia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04229374	0	2021-05-31	2021-05-31	MAH	2021611951	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
37 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ATIVAN	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
QUETIAPINE	Concomitant	Tablets					
VALTREX	Concomitant						
WELLBUTRIN	Concomitant	TABLET (EXTENDED-RELEASE)					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Intermenstrual bleeding	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Ovarian cyst ruptured	v.24.1	
Pruritus	v.24.1	
Skin exfoliation	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04230331	0	2021-06-01	2021-06-01	MAH	2021A477716	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.24.1	
Lymphadenopathy	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04230872	4	2021-06-01	2021-08-20	MAH	MOD-2021-143418	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
62 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	1.0 Dosage forms			COVID-19 immunisation
VITAMINS NOS	Concomitant						Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Bedridden	v.24.1	5 Weeks
Chest discomfort	v.24.1	38 Days

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.24.1	
Dry mouth	v.24.1	
Dysphagia	v.24.1	38 Days
Fatigue	v.24.1	
Feeling hot	v.24.1	38 Days
Headache	v.24.1	38 Days
Hypertension	v.24.1	-90
Hyperventilation	v.24.1	
Incomplete course of vaccination	v.24.1	
Malaise	v.24.1	
Product availability issue	v.24.1	
Product dose omission issue	v.24.1	
Suffocation feeling	v.24.1	
Tachycardia	v.24.1	38 Days
Thirst	v.24.1	
Throat tightness	v.24.1	38 Days
Tongue dry	v.24.1	
Vaccination complication	v.24.1	38 Days
Vaccination site swelling	v.24.1	
Vascular headache	v.24.1	11 Days
Vasoconstriction	v.24.1	38 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04231147	0	2021-06-01	2021-06-01	MAH	2021612069	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
32 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Depressed mood	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04231155	1	2021-06-01	2021-08-02	MAH	2021556177	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
56 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
FORMOTEROL FUMARATE/MOMETASONE FUROATE	Concomitant						
NASONEX	Concomitant	SPRAY, METERED DOSE					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain upper	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Diarrhoea	v.24.1	
Diarrhoea haemorrhagic	v.24.1	
Fatigue	v.24.1	
Flatulence	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04231160	2	2021-06-01	2021-07-15	MAH	2021555778	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
31 Years	Female	157 Centimeter	56 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ELTROXIN	Concomitant	Tablets	Oral				Hypothyroidism
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abortion spontaneous	v.24.1	162 Hours

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04231218	2	2021-06-01	2021-07-26	MAH	2021583280	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
55 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Deafness	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04231287	1	2021-06-01	2021-07-13	MAH	2021612611	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
53 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ENBREL	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Rheumatoid arthritis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04232066	1	2021-06-01	2021-06-30	MAH	2021590976	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
60 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.24.1	
Heart rate increased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04232102	1	2021-06-01	2021-06-14	MAH	2021556296	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
53 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CIPRALEX [ESCITALOPRAM]	Concomitant						
CONCERTA	Concomitant	TABLET (EXTENDED-RELEASE)					
GABAPENTIN	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
SERRAPEPTASE	Concomitant	Capsules					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthritis	v.24.1	
Autoimmune disorder	v.24.1	
Colitis	v.24.1	
Condition aggravated	v.24.1	
Crohn's disease	v.24.1	
Diarrhoea	v.24.1	
Fibromyalgia	v.24.1	
Headache	v.24.1	
Irritable bowel syndrome	v.24.1	
Neuralgia	v.24.1	
Sleep disorder	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04232129	1	2021-06-01	2021-07-12	MAH	2021556935	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
67 Years				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
SYNTHROID	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bell's palsy	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04232164	0	2021-06-01	2021-06-01	MAH	2021592260	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
26 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Decreased appetite	v.24.1	
Diarrhoea	v.24.1	
Fatigue	v.24.1	
Headache	v.24.1	
Pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04232522	2	2021-06-01	2021-07-30	MAH	2021562838	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
85 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PANTOPRAZOLE	Concomitant	NOT SPECIFIED	Oral	40.0 Milligram	1 every 1 Days		Prophylaxis
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
RAMIPRIL	Concomitant	NOT SPECIFIED	Oral	1.0 Dosage forms	1 every 1 Days		Blood pressure abnormal
ROSUVASTATIN	Concomitant	NOT SPECIFIED	Oral	1.0 Dosage forms	1 every 1 Days		Hypercholesterolaemia

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	
Transient ischaemic attack	v.24.1	-124

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04233323	2	2021-06-01	2021-09-16	MAH	2021559937	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
34 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASCORBIC ACID/FOLIC ACID/NICOTINIC ACID/PYRIDOXINE HYDROCHLORIDE/VITAMIN A/RIBOFLAVIN/VITAMIN B1/VITAMIN B12/VITAMIN D/VITAMIN E	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.24.1	1 Months

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	1 Months
Headache	v.24.1	1 Months
Rash	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04233334	1	2021-06-01	2021-06-15	MAH	2021612052	Spontaneous	Consumer/other non health professional

Serious report?
Serious

Death:	No	**Disability:**	No	**Congenital Anomaly:**	No
Life Threatening:	No	**Hospitalization:**	No	**Other Medically Important Conditions:**	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
36 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	
Linked	
Linked	
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
DROSPIRENONE/ETHINYL ESTRADIOL	Concomitant						Contraception
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Dizziness	v.24.1	
Fatigue	v.24.1	
Food craving	v.24.1	
Food poisoning	v.24.1	
Nausea	v.24.1	
Pain in extremity	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04234061	0	2021-06-01	2021-06-01	MAH	MOD-2021-161974	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	1.0 Dosage forms			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Dizziness	v.24.1	
Hypoaesthesia	v.24.1	
Vasculitis	v.24.1	
Weight decreased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04234231	0	2021-06-01	2021-06-01	MAH	2021TUS034476	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				COVID-19 immunisation
CUVITRU NORMAL IMMUNE GLOBULIN (HUMAN). SINGLE-DOSE VIALS	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Transient ischaemic attack	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04234341	2	2021-06-01	2021-07-26	MAH	2021592689	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
65 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CHLOROTHIAZIDE	Concomitant	NOT SPECIFIED		1.0 Dosage forms	every 1 Days		
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
SYNTHROID	Concomitant	NOT SPECIFIED		0.137 Milligram	every 1 Days		
TELMISARTAN	Concomitant	Tablets		40.0 Milligram	every 1 Days		Blood pressure management
VITAMIN D	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bell's palsy	v.24.1	
Ear pain	v.24.1	5 Minutes

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	
Headache	v.24.1	
Visual impairment	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04234790	0	2021-06-01	2021-06-01	MAH	2021563399	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
19 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BENADRYL	Concomitant	NOT SPECIFIED					
CETIRIZINE HYDROCHLORIDE	Concomitant						
CONCERTA	Concomitant	TABLET (EXTENDED-RELEASE)					
LOLO	Concomitant	Tablets					
MELATONIN	Concomitant	Capsule					
OMEGA-3	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular			1.0 Days	COVID-19 immunisation
PROBIOTICS NOS	Concomitant						
SINGULAIR	Concomitant	NOT SPECIFIED					
VITAMIN C	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pruritus	v.24.1	
Rash maculo-papular	v.24.1	
Skin burning sensation	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04235051	0	2021-06-01	2021-06-01	MAH	2021A484397	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Thrombocytopenia	v.24.1	
Thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04235062	1	2021-06-01	2021-06-04	MAH	2021A473071	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Thrombocytopenia	v.24.1	
Thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04238338	1	2021-06-02	2021-06-21	MAH	MOD-2021-181916	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
63 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	1.0 Dosage forms			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthritis	v.24.1	
Bone pain	v.24.1	
Influenza like illness	v.24.1	
Major depression	v.24.1	
Somnolence	v.24.1	
Suicidal ideation	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04240919	0	2021-06-02	2021-06-02	MAH	2021465428	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown				COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04240937	1	2021-06-02	2021-06-10	MAH	2021131076	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
60 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Urinary tract infection	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04241287	0	2021-06-02	2021-06-02	MAH	2021612859	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
52 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Ageusia	v.24.1	
Anosmia	v.24.1	
Chest pain	v.24.1	
Epistaxis	v.24.1	
Hypothyroidism	v.24.1	
Somnolence	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04241350	0	2021-06-02	2021-06-02	MAH	2021619773	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
94 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Back pain	v.24.1	
Dysstasia	v.24.1	
General physical health deterioration	v.24.1	
Pyrexia	v.24.1	
Rales	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04241373	2	2021-06-02	2021-06-25	MAH	2021612591	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
54 Years	Female	15 Centimeter	54 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
SYNTHROID	Concomitant	NOT SPECIFIED		75.0 Microgram			Hypothyroidism
VITAMIN B-COMPLEX [VITAMIN B COMPLEX]	Concomitant						Prophylaxis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.24.1	0 Months
Fatigue	v.24.1	
Feeling abnormal	v.24.1	6 Hours

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Feeling drunk	v.24.1	4 Hours
Headache	v.24.1	46 Hours
Heavy menstrual bleeding	v.24.1	4 Days
Migraine	v.24.1	46 Hours
Neck pain	v.24.1	0 Months

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04241387	1	2021-06-02	2021-09-10	MAH	2021612475	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
78 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	0.0	COVID-19 immunisation
VYNDAQEL	Concomitant	Capsules	Oral	80.0 Milligram	every 1 Days		Cardiac amyloidosis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.24.1	
Drug ineffective	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04241410	0	2021-06-02	2021-06-02	MAH	2021612934	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
71 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CHLORTHALIDONE	Concomitant	Tablets		16.0 Milligram			
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Gout	v.24.1	
Oedema peripheral	v.24.1	-105
Pain	v.24.1	
Pyrexia	v.24.1	20 Hours

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04241433	1	2021-06-02	2021-07-20	MAH	2021570419	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
55 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
THYROID	Concomitant						Hypothyroidism

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Nausea	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04241456	1	2021-06-02	2021-07-14	MAH	2021568258	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
40 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Contusion	v.24.1	
Platelet count decreased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04241462	0	2021-06-02	2021-06-02	MAH	2021598544	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
52 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
INSULIN ASPART	Concomitant		Subcutaneous				Type 1 diabetes mellitus
LANTUS	Concomitant	SOLUTION SUBCUTANEOUS	Subcutaneous				Type 1 diabetes mellitus
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypoglycaemia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04241469	2	2021-06-02	2021-09-14	MAH	2021619438	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
74 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Decreased appetite	v.24.1	
Diplopia	v.24.1	
Gait disturbance	v.24.1	
Nausea	v.24.1	
Weight decreased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04243111	0	2021-06-03	2021-06-03	MAH	2021BI01017126	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
34 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AVONEX PREFILLED SYRINGE, PREFILLED AUTOINJECTOR	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	30.0 Microgram	1 every 1 Weeks		Multiple sclerosis
COVID-19 VACCINE	Suspect		Unknown				COVID-19 prophylaxis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Multiple sclerosis relapse	v.24.1	
Vaccination complication	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04244260	0	2021-06-03	2021-06-03	MAH	MOD-2021-074948	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
56 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BUDESONIDE/FORMOTEROL FUMARATE	Concomitant		Unknown	200.0 Dosage forms	2 every 1 Days		Chronic obstructive pulmonary disease
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	1.0 Dosage forms			COVID-19 immunisation
EPIPEN JR 0.15MG/0.3ML AUTO-INJECTOR	Concomitant	SOLUTION INTRAMUSCULAR	Unknown				Product used for unknown indication
LECTOPAM	Concomitant	Tablets	Unknown	6.0 Milligram	1 every 1 Days		Sleep disorder
MAGNESIUM	Concomitant	NOT SPECIFIED	Unknown	250.0 Dosage forms	1 every 1 Days		Muscle spasms

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PANTOLOC [PANTOPRAZOLE]	Concomitant		Unknown	40.0 Milligram	1 every 1 Days		Dyspepsia

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.24.1	36 Hours
Condition aggravated	v.24.1	5 Days
Pain in extremity	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04246536	1	2021-06-03	2021-09-17	MAH	2021568243	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
54 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain upper	v.24.1	
Arthralgia	v.24.1	
Blood pressure decreased	v.24.1	
Blood pressure fluctuation	v.24.1	
Diarrhoea	v.24.1	
Eating disorder	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	
Feeling abnormal	v.24.1	
Insomnia	v.24.1	
Muscle spasms	v.24.1	
Myalgia	v.24.1	
Pain	v.24.1	
Syncope	v.24.1	
Tenderness	v.24.1	
Tremor	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04246618	1	2021-06-03	2021-07-23	MAH	2021536057	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
62 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.24.1	
Drug ineffective	v.24.1	
Illness	v.24.1	
Malaise	v.24.1	
Stress	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04246823	1	2021-06-03	2021-06-25	MAH	2021619137	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
45 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.24.1	-115
Fatigue	v.24.1	-115
Pyrexia	v.24.1	-142
Pyrexia	v.24.1	2 Days
Vaccination site pain	v.24.1	-115

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04247066	0	2021-06-03	2021-06-03	MAH	2021612920	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
40 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
NUVARING	Concomitant	RING (SLOW-RELEASE)					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Heavy menstrual bleeding	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04247068	1	2021-06-03	2021-07-19	MAH	2021571274	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
43 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Agitation	v.24.1	
Cardiac flutter	v.24.1	
Chest pain	v.24.1	
Dysgeusia	v.24.1	
Headache	v.24.1	
Heart rate increased	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Insomnia	v.24.1	
Palpitations	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04247318	2	2021-06-03	2021-07-15	MAH	2021575501	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chronic leukaemia	v.24.1	
Inappropriate schedule of product administration	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04247380	0	2021-06-03	2021-06-03	MAH	2021605447	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
52 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Diarrhoea	v.24.1	
Fatigue	v.24.1	
Head discomfort	v.24.1	
Headache	v.24.1	
Nausea	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pain in extremity	v.24.1	11 Hours
Pyrexia	v.24.1	7 Days
Tinnitus	v.24.1	
Vomiting	v.24.1	3 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04247418	1	2021-06-03	2021-07-17	MAH	2021612893	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
12 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Syncope	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04247771	1	2021-06-03	2021-07-21	MAH	2021575782	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
59 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Back pain	v.24.1	
Gastrointestinal pain	v.24.1	
Pain in extremity	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04249995	0	2021-06-04	2021-06-04	MAH	MOD-2021-187264	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
61 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	1.0 Dosage forms			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest discomfort	v.24.1	8 Days
Gastrointestinal disorder	v.24.1	8 Days
Muscle spasms	v.24.1	8 Days
Pain in extremity	v.24.1	4 Days
Pericarditis	v.24.1	7 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04250343	1	2021-06-04	2021-06-18	MAH	MOD-2021-177126	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
66 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	1.0 Dosage forms			COVID-19 immunisation
INSULIN	Concomitant	GLOBULES ORAL	Subcutaneous	1.0 Dosage forms			Diabetes mellitus
RAMIPRIL	Concomitant	NOT SPECIFIED	Oral		2 every 1 Days		Supplementation therapy
SYNTHROID	Concomitant	NOT SPECIFIED	Oral		1 every 1 Days		Hypothyroidism

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.24.1	
Fatigue	v.24.1	
Headache	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Malaise	v.24.1	
Myalgia	v.24.1	
Nausea	v.24.1	
Pain in extremity	v.24.1	
Pneumonia bacterial	v.24.1	
Pyrexia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04250739	0	2021-06-04	2021-06-04	MAH	MOD-2021-182886	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
57 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	1.0 Dosage forms			COVID-19 immunisation
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	Injection	Intramuscular	1.0 Dosage forms			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Burning sensation	v.24.1	
Coordination abnormal	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypoaesthesia	v.24.1	
Insomnia	v.24.1	
Multiple sclerosis	v.24.1	
Speech disorder	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04251070	0	2021-06-04	2021-06-04	MAH	MOD-2021-096017	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
29 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Unknown	1.0 Dosage forms			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.24.1	9 Days
Cough	v.24.1	9 Days
Dysphagia	v.24.1	9 Days
Fatigue	v.24.1	
Feeling hot	v.24.1	9 Days
Nasal congestion	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Nausea	v.24.1	9 Days
Oropharyngeal pain	v.24.1	
Palpitations	v.24.1	9 Days
Pyrexia	v.24.1	
Throat tightness	v.24.1	9 Days
Vomiting	v.24.1	9 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04251235	0	2021-06-04	2021-06-04	MAH	MOD-2021-175039	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
58 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	1.0 Dosage forms			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pyrexia	v.24.1	
Sepsis	v.24.1	
Vaccination site rash	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04252446	1	2021-06-04	2021-06-16	MAH	2021576736	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
74 Years	Female	152 Centimeter	72 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest discomfort	v.24.1	1 Days
Chest pain	v.24.1	
Diarrhoea	v.24.1	1 Days
Dysphonia	v.24.1	
Dyspnoea	v.24.1	1 Days
Dysstasia	v.24.1	1 Days

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	
Feeling abnormal	v.24.1	1 Days
Hypoaesthesia	v.24.1	1 Days
Influenza like illness	v.24.1	1 Days
Palpitations	v.24.1	1 Days
Rash	v.24.1	
Tremor	v.24.1	1 Days
Visual impairment	v.24.1	1 Days
Vomiting	v.24.1	1 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04252499	0	2021-06-04	2021-06-04	MAH	2021618991	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
WELLBUTRIN	Concomitant	TABLET (EXTENDED-RELEASE)					Affective disorder

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal discomfort	v.24.1	
Chills	v.24.1	
Diarrhoea	v.24.1	
Pain	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pyrexia	v.24.1	
Rash	v.24.1	
Urticaria	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04252751	0	2021-06-04	2021-06-04	MAH	2021619427	Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
20 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Generalised tonic-clonic seizure	v.24.1	
Presyncope	v.24.1	
Syncope	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04252784	0	2021-06-04	2021-06-04	MAH	2021612568	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
21 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
B12 [CYANOCOBALAMIN]	Concomitant						
ETHINYL ESTRADIOL/LEVONORGESTREL	Concomitant						
FORMOTEROL FUMARATE/MOMETASONE FUROATE	Concomitant						
IRON	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
VENLAFAXINE	Concomitant						
VENTOLIN [SALBUTAMOL]	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Burning sensation	v.24.1	
Deafness	v.24.1	
Dizziness	v.24.1	
Dyspnoea	v.24.1	
Paraesthesia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04252785	0	2021-06-04	2021-06-04	MAH	2021619163	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
28 Years				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	
Herpes zoster	v.24.1	
Lymphadenopathy	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04252912	0	2021-06-04	2021-06-04	MAH	2021619570	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
39 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Appendicitis	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Off label use	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04252914	1	2021-06-04	2021-07-21	MAH	2021583467	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
43 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain lower	v.24.1	
Chills	v.24.1	
Confusional state	v.24.1	
Decreased appetite	v.24.1	
Fatigue	v.24.1	
Gait disturbance	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Vaccination site pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04252922	0	2021-06-04	2021-06-04	MAH	2021619686	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
52 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Decreased appetite	v.24.1	
Disease recurrence	v.24.1	
Dizziness	v.24.1	
Fatigue	v.24.1	
Headache	v.24.1	
Nausea	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pain	v.24.1	
Vaccination site movement impairment	v.24.1	
Vaccination site pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04252926	0	2021-06-04	2021-06-04	MAH	2021583153	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
53 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain upper	v.24.1	
Postmenopausal haemorrhage	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04252984	1	2021-06-04	2021-07-19	MAH	2021619518	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
42 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Erectile dysfunction	v.24.1	
Libido decreased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04253025	1	2021-06-04	2021-08-10	MAH	2021619415	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abortion spontaneous	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04253477	1	2021-06-04	2021-06-22	MAH	2021390660	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
88 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BCG VACCINE LIVE INTRAVESICAL (RIVM)	Concomitant						Bladder cancer
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
TOVIAZ	Suspect	TABLET (EXTENDED-RELEASE)	Unknown	8.0 Milligram			Product used for unknown indication
TRAZODONE	Concomitant						Antidepressant therapy

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain upper	v.24.1	-90
Constipation	v.24.1	-90
Gastrointestinal obstruction	v.24.1	-90
Insomnia	v.24.1	-90
Palpitations	v.24.1	-90
Vomiting	v.24.1	-92

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04253484	1	2021-06-04	2021-09-16	MAH	2021559746	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
67 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.24.1	
Drug ineffective	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04253497	1	2021-06-04	2021-09-17	MAH	2021559745	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
84 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.24.1	
Drug ineffective	v.24.1	
Illness	v.24.1	
Malaise	v.24.1	
Stress	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04253604	0	2021-06-04	2021-06-04	MAH	2021581839	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
26 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Loss of consciousness	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04253612	0	2021-06-04	2021-06-04	MAH	2021581991	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
42 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown			1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Fatigue	v.24.1	
Myalgia	v.24.1	
Night sweats	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04254575	1	2021-06-05	2021-06-24	MAH	MOD-2021-190039	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
38 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Unknown	1.0 Dosage forms			COVID-19 immunisation
CYANOCOBALAMIN	Concomitant						Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain upper	v.24.1	
Agitation	v.24.1	
Coeliac disease	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Condition aggravated	v.24.1	
Constipation	v.24.1	
Fatigue	v.24.1	
Gastric dilatation	v.24.1	
Illness	v.24.1	
Myalgia	v.24.1	
Pruritus	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04254889	2	2021-06-05	2021-07-30	MAH	2021619651	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
31 Years	Female	201 Centimeter	52 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
IBUPROFEN	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
TYLENOL	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Decreased appetite	v.24.1	65 Hours
Diarrhoea	v.24.1	65 Hours
Disturbance in attention	v.24.1	137 Hours
Syncope	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04254961	0	2021-06-05	2021-06-05	MAH	2021583774	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
80 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Hypoaesthesia	v.24.1	
Pain in extremity	v.24.1	
Peripheral swelling	v.24.1	
Pyrexia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04255019	0	2021-06-05	2021-06-05	MAH	2021619618	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
24 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Meniere's disease	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04258125	0	2021-06-07	2021-06-07	MAH	MOD-2021-182696	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
65 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	1.0 Dosage forms			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Angina pectoris	v.24.1	
Depression	v.24.1	
Dizziness	v.24.1	
Headache	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04259227	0	2021-06-07	2021-06-07	MAH	21K-028-3926782-00	Study	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
64 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular			1.0 Months	COVID-19 immunisation
HUMIRA	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous	40.0 Milligram	1 every 2 Weeks		Colitis ulcerative

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cardiac disorder	v.24.1	
Herpes zoster	v.24.1	
Nephrolithiasis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04259574	0	2021-06-07	2021-06-07	MAH	2021585114	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
49 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BACLOFEN	Suspect	NOT SPECIFIED	Unknown				Product used for unknown indication
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	
Herpes simplex	v.24.1	
Influenza	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04259901	0	2021-06-07	2021-06-07	MAH	2021584817	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
28 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.24.1	
Decreased appetite	v.24.1	
Dizziness	v.24.1	
Fatigue	v.24.1	
Flushing	v.24.1	
Haemoptysis	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Nausea	v.24.1	
Off label use	v.24.1	
Oropharyngeal pain	v.24.1	
Pain	v.24.1	
Presyncope	v.24.1	
Vertigo	v.24.1	
Vision blurred	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04260180	0	2021-06-07	2021-06-07	MAH	MOD-2021-190199	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
38 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	1.0 Dosage forms			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Coeliac disease	v.24.1	
Condition aggravated	v.24.1	
Myalgia	v.24.1	
Nausea	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04260736	1	2021-06-07	2021-07-19	MAH	2021641593	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
78 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	
Haemolytic anaemia	v.24.1	
Insomnia	v.24.1	
Malaise	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04260815	0	2021-06-07	2021-06-07	MAH	2021585045	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
39 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BUDESONIDE/FORMOTEROL FUMARATE	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
SALBUTAMOL	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dyskinesia	v.24.1	
Headache	v.24.1	
Loss of consciousness	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Malaise	v.24.1	
Movement disorder	v.24.1	
Pyrexia	v.24.1	
Somnolence	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04261782	0	2021-06-08	2021-06-08	MAH	21K-028-3931335-00	Study	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
25 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular			-120.0	COVID-19 immunisation
HUMIRA	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous	40.0 Milligram	1 every 2 Weeks		Crohn's disease

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.24.1	1 Months
Hypoaesthesia	v.24.1	1 Months
Pain	v.24.1	1 Months
Therapeutic product effect decreased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04263319	4	2021-06-08	2021-11-09	MAH	CA2021AMR097857	Study	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
38 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_02657283
Linked	
Linked	
Linked	E2B_02235132
Linked	
Linked	E2B_01887821
Linked	E2B_01289794
Linked	
Linked	
Linked	E2B_03520088
Linked	E2B_03145071
Linked	E2B_02702305
Linked	E2B_02690606
Linked	E2B_02657283
Linked	
Linked	

Record Type	Link AER** Number
Linked	E2B_02235132
Linked	
Linked	E2B_01887821
Linked	E2B_01289794
Linked	
Linked	
Linked	E2B_03520088
Linked	E2B_03145071
Linked	E2B_02702305
Linked	E2B_02690606
Linked	E2B_02657283
Linked	
Linked	
Linked	E2B_02235132
Linked	
Linked	E2B_01887821
Linked	E2B_01289794
Linked	
Linked	
Linked	E2B_03520088
Linked	E2B_03145071
Linked	E2B_02702305
Linked	E2B_02690606
Linked	E2B_02657283
Linked	
Linked	
Linked	E2B_02235132
Linked	
Linked	E2B_01887821
Linked	E2B_01289794
Linked	
Linked	
Linked	E2B_03520088
Linked	E2B_03145071
Linked	E2B_02702305

Record Type	Link AER** Number
Linked	E2B_02690606
Linked	E2B_02657283
Linked	
Linked	
Linked	E2B_02235132
Linked	
Linked	E2B_01887821
Linked	E2B_01289794
Linked	
Linked	
Linked	E2B_03520088
Linked	E2B_03145071
Linked	E2B_02702305
Linked	E2B_02690606
Linked	E2B_04984988
Linked	E2B_04984988

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ADVAIR	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication
ALVESCO	Concomitant	AEROSOL, METERED DOSE	Unknown				Product used for unknown indication
ATROVENT	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication
COVID-19 VACCINE	Suspect		Unknown				Product used for unknown indication, COVID-19 prophylaxis
COVID-19 VACCINE	Suspect		Unknown				Product used for unknown indication, COVID-19 prophylaxis

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
HYDROMORPH CONTIN	Concomitant	CAPSULE, SUSTAINED-RELEASE	Unknown				Product used for unknown indication
HYDROMORPHONE	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication
IRON	Concomitant		Unknown				Product used for unknown indication
LYRICA	Concomitant	Capsules	Unknown				Product used for unknown indication
MAGNESIUM	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication
MEPOLIZUMAB	Suspect		Subcutaneous	100.0 Milligram			Product used for unknown indication, Asthma
MEPOLIZUMAB	Suspect	Powder for injection	Subcutaneous	100.0 Milligram			Product used for unknown indication, Asthma
MEPOLIZUMAB	Suspect	Powder for injection	Subcutaneous	100.0 Milligram			Product used for unknown indication, Asthma
MONTELUKAST	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication
OMALIZUMAB	Suspect	NOT SPECIFIED	Unknown				Product used for unknown indication
PENTALOC	Concomitant		Unknown				Product used for unknown indication
PREDNISONE	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication
PREGABALIN	Concomitant	Capsules	Unknown				Product used for unknown indication

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PROZAC	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication
TRAZODONE	Concomitant		Unknown				Product used for unknown indication
VENTOLIN	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication
XARELTO	Concomitant	Coated tablet	Unknown				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Carpal tunnel syndrome	v.24.1	
Catheter site injury	v.24.1	
Chills	v.24.1	3 Days
Fatigue	v.24.1	
Headache	v.24.1	
Heart rate increased	v.24.1	
Impaired gastric emptying	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Influenza like illness	v.24.1	
Product dose omission issue	v.24.1	
Skin infection	v.24.1	
Tachycardia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04265187	0	2021-06-08	2021-06-08	MAH	2021A500439	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
44 Years	Female	155 Centimeter	89 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular			1.0 Days	Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blepharospasm	v.24.1	
Dizziness	v.24.1	
Eye injury	v.24.1	41 Days
Eye pain	v.24.1	
Facial pain	v.24.1	41 Days
Headache	v.24.1	
Photophobia	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pupillary disorder	v.24.1	
Pupillary light reflex tests abnormal	v.24.1	
Pyrexia	v.24.1	
Tinnitus	v.24.1	41 Days
Vaccination site rash	v.24.1	
Vision blurred	v.24.1	41 Days
Visual impairment	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04265378	0	2021-06-08	2021-06-08	MAH	2021594581	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
39 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CETIRIZINE HYDROCHLORIDE	Concomitant						
ESCITALOPRAM OXALATE	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal distension	v.24.1	
Abdominal pain upper	v.24.1	
Diarrhoea	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.24.1	
Fatigue	v.24.1	
Night sweats	v.24.1	
Syncope	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04265498	1	2021-06-08	2021-07-22	MAH	2021620512	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
32 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
WELLBUTRIN	Concomitant	TABLET (EXTENDED-RELEASE)					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Vertigo	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04265865	1	2021-06-08	2021-09-17	MAH	2021607115	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.24.1	
Drug ineffective	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04266145	0	2021-06-08	2021-06-08	MAH	2021592732	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
29 Years	Female			Recovered/resolved with sequelae

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abortion spontaneous	v.24.1	
Drug exposure before pregnancy	v.24.1	
Extra dose administered	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Pregnancy on contraceptive	v.24.1	-58

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04266387	0	2021-06-08	2021-06-08	MAH	2021599491	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
46 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ERGOCALCIFEROL	Concomitant						
FOSFOMYCIN TROMETAMOL	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
POLYCARBOPHIL CALCIUM	Concomitant						
VITAMIN C/ZINC	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Erectile dysfunction	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04266458	0	2021-06-08	2021-06-08	MAH	2021593525	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
25 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Ageusia	v.24.1	
Bell's palsy	v.24.1	
Headache	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04266469	2	2021-06-08	2021-06-28	MAH	2021619710	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
52 Years	Female			Recovered/resolved with sequelae

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
FLOVENT	Concomitant	NOT SPECIFIED	Inhalation		As required		Asthma
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.24.1	
Aphasia	v.24.1	
Dyspnoea	v.24.1	
Heart rate increased	v.24.1	
Hypertension	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04266671	1	2021-06-08	2021-06-21	MAH	2021605671	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
56 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hepatitis	v.24.1	
Pancreatitis	v.24.1	
Splenitis	v.24.1	
Thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04266696	1	2021-06-08	2021-08-31	MAH	2021593257	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
48 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
B12 [MECOBALAMIN]	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
SULFATRIM DS	Concomitant	Tablets					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cataplexy	v.24.1	
Narcolepsy	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04267312	1	2021-06-08	2021-06-23	MAH	2021599122	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
54 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CANNABIDIOL	Concomitant		Oral			7.0 Months	Pain
CONCERTA	Concomitant	TABLET (EXTENDED-RELEASE)	Oral	36.0 Milligram	1 every 1 Days		Sleep terror, Attention deficit hyperactivity disorder
CONCERTA	Concomitant		Oral	36.0 Milligram	1 every 1 Days		Sleep terror, Attention deficit hyperactivity disorder
PANTOPRAZOLE	Concomitant	NOT SPECIFIED	Oral	40.0 Milligram	1 every 1 Days		Gastrooesophageal reflux disease

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
ROSUVASTATIN	Concomitant	NOT SPECIFIED	Oral	20.0 Milligram	1 every 1 Days		Hypercholesterolaemia
XARELTO	Concomitant	Coated tablet	Oral	15.0 Milligram	1 every 1 Days	31.0 Days	Hip arthroplasty

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.24.1	
Pulmonary thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04268100	1	2021-06-09	2021-06-09	MAH	21K-028-3928631-00	Study	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
72 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular			1.0 Days	COVID-19 immunisation
HUMIRA	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous	40.0 Milligram	1 every 2 Weeks		Rheumatoid arthritis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fall	v.24.1	1 Months
Fatigue	v.24.1	-90
Joint range of motion decreased	v.24.1	
Lung disorder	v.24.1	366
Pain	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pleural effusion	v.24.1	366

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04268111	0	2021-06-09	2021-06-09	MAH	21K-028-3928994-00	Study	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
56 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular			1.0 Months	COVID-19 immunisation
HUMIRA	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous	40.0 Milligram	1 every 2 Weeks	10.0 Years	Rheumatoid arthritis
HUMIRA	Suspect	Solution for injection in pre-filled pen	Subcutaneous	40.0 Milligram	1 every 2 Weeks		Rheumatoid arthritis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Aphonia	v.24.1	
Chills	v.24.1	
Cough	v.24.1	
Illness	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Oropharyngeal pain	v.24.1	5 Days
Pyrexia	v.24.1	0
Vaginal abscess	v.24.1	
Vaginal infection	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04269929	3	2021-06-09	2021-07-21	MAH	2021619232	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
68 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dysarthria	v.24.1	1 Months
Facial paralysis	v.24.1	1 Months

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04270183	0	2021-06-09	2021-06-09	MAH	2021600367	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
37 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.24.1	
Pericarditis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04270362	0	2021-06-09	2021-06-09	MAH	2021599101	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
67 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AMLODIPINE BESILATE	Concomitant			5.0 Milligram	1 every 1 Days		
CLARITIN [CLARITHROMYCIN]	Concomitant				every 1 Days		
GLICLAZIDE MR	Concomitant	TABLET (EXTENDED-RELEASE)		60.0 Milligram	every 1 Days		
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
RAMIPRIL	Concomitant	NOT SPECIFIED		10.0 Milligram	every 1 Days		
ROSUVASTATIN CALCIUM	Concomitant			10.0 Milligram	every 1 Days		
SALBUTAMOL HFA	Concomitant	METERED-DOSE (AEROSOL)		100.0 Microgram	As required		
SITAGLIPTIN	Concomitant			100.0 Milligram	1 every 1 Days		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pericarditis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04270463	1	2021-06-09	2021-07-26	MAH	2021633871	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
37 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CIPRALEX [ESCITALOPRAM]	Concomitant		Oral				Anxiety
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
SYNTHROID	Concomitant	NOT SPECIFIED	Oral				Hypothyroidism

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Back pain	v.24.1	
Dizziness	v.24.1	7 Hours
Gait disturbance	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Loss of personal independence in daily activities	v.24.1	
Movement disorder	v.24.1	
Pain in extremity	v.24.1	7 Hours

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04270477	2	2021-06-09	2021-06-24	MAH	2021634648	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
52 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bell's palsy	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04270574	1	2021-06-09	2021-07-30	MAH	2021633847	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
41 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Back pain	v.24.1	13 Days
Hypokinesia	v.24.1	13 Days
Insomnia	v.24.1	13 Days
Paraesthesia	v.24.1	13 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04270577	1	2021-06-09	2021-06-24	MAH	2021633953	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
26 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pallor	v.24.1	0 Months
Syncope	v.24.1	0 Months

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04270595	1	2021-06-09	2021-08-16	MAH	2021SA126984	Study	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
57 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BETADERM	Concomitant	NOT SPECIFIED	Unknown				
CHLOROCRESOL/CLOBETASONE BUTYRATE	Concomitant		Unknown				
CICLOSPORIN	Concomitant	NOT SPECIFIED	Unknown				
COVID-19 VACCINE	Suspect		Unknown				COVID-19 immunisation
DUPILUMAB	Suspect	Solution for injection	Subcutaneous	300.0 Milligram	1 every 2 Weeks	1.0 Months	Dermatitis atopic
DUPILUMAB	Suspect		Subcutaneous	600.0 Milligram	Total	1.0 Days	Dermatitis atopic
EPIPEN 0.3MG/0.3ML AUTO-INJECTOR	Concomitant		Unknown				Eczema
EPIPEN 0.3MG/0.3ML AUTO-INJECTOR	Concomitant	SOLUTION INTRAMUSCULAR	Unknown				Eczema
PREDNISONE	Concomitant	NOT SPECIFIED	Unknown				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Cataract	v.24.1	
Condition aggravated	v.24.1	
Condition aggravated	v.24.1	
Condition aggravated	v.24.1	
Condition aggravated	v.24.1	
Diarrhoea	v.24.1	1 Days
Eye pain	v.24.1	
Eye pruritus	v.24.1	
Eye swelling	v.24.1	
Feeling abnormal	v.24.1	1 Months
Headache	v.24.1	
Injection site pain	v.24.1	1 Months
Injection site swelling	v.24.1	1 Months
Injury corneal	v.24.1	
Lacrimation increased	v.24.1	
Ocular hyperaemia	v.24.1	
Phobia of driving	v.24.1	
Vision blurred	v.24.1	
Visual impairment	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04270655	1	2021-06-09	2021-07-19	MAH	2021605536	Spontaneous	Physician

Serious report?	Death:	Disability:	Congenital Anomaly:
Serious	Yes	No	No
	Life Threatening: No	**Hospitalization:** Yes	**Other Medically Important Conditions:** Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
72 Years	Male			Fatal

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular			1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cerebral thrombosis	v.24.1	
Headache	v.24.1	
Loss of consciousness	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04271010	1	2021-06-09	2021-06-17	MAH	2021605951	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
58 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Guillain-Barre syndrome	v.24.1	
Paraesthesia	v.24.1	
Vaccination site pain	v.24.1	24 Hours

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04271013	1	2021-06-09	2021-06-24	MAH	2021607094	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
58 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
GLICLAZIDE	Concomitant	Tablets		30.0 Milligram	1 every 1 Days		
METFORMIN	Concomitant			500.0 Milligram	2 every 1 Days		
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cerebrovascular accident	v.24.1	
Hypoaesthesia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04271071	0	2021-06-09	2021-06-09	MAH	2021606136	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
37 Years	Female			Recovered/resolved with sequelae

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Months	COVID-19 immunisation
SYNTHROID	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bell's palsy	v.24.1	-91

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04271888	1	2021-06-09	2021-07-02	MAH	2021A484398	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
63 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	
Pain in extremity	v.24.1	
Pruritus	v.24.1	
Rash	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04271958	1	2021-06-09	2021-07-21	MAH	2021620561	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
51 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MIRTAZAPINE	Concomitant	Tablets		3.75 Milligram			
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Meniere's disease	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04272040	0	2021-06-09	2021-06-09	MAH	2021607057	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
43 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ESCITALOPRAM	Concomitant	Tablets					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
ROSUVASTATIN	Concomitant	NOT SPECIFIED					
VITAMIN B12	Concomitant						
WELLBUTRIN	Concomitant	TABLET (EXTENDED-RELEASE)					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Nausea	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Vertigo	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04272080	1	2021-06-09	2021-07-28	MAH	2021607153	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
47 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Chest pain	v.24.1	
Dizziness	v.24.1	
Dyspnoea	v.24.1	
Fatigue	v.24.1	
Feeling abnormal	v.24.1	
Heart rate increased	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Muscle spasms	v.24.1	
Off label use	v.24.1	
Presyncope	v.24.1	
Product use issue	v.24.1	
Rash	v.24.1	14 Days
Somnolence	v.24.1	
Swollen tongue	v.24.1	
Yawning	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04272601	0	2021-06-09	2021-06-09	MAH	2021608190	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
40 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
DESOGESTREL/ETHINYL ESTRADIOL	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
SERTRALINE	Concomitant	Capsules					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Myocarditis	v.24.1	60 Hours
Palpitations	v.24.1	60 Hours

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04272625	1	2021-06-09	2021-07-21	MAH	2021606332	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
50 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Heavy menstrual bleeding	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04272855	0	2021-06-09	2021-06-09	MAH	2843894	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
54 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETAMINOPHEN/OXYCODONE HYDROCHLORIDE	Concomitant						Pain
ACTEMRA	Suspect	Solution for infusion	Intravenous (not otherwise specified)	640.0 Milligram	1 every 4 Weeks	295.0 Days	Rheumatoid arthritis
ACTEMRA	Suspect	Solution for infusion	Intravenous (not otherwise specified)	600.0 Milligram	1 every 4 Weeks		Rheumatoid arthritis
ACTEMRA	Suspect	NOT SPECIFIED	Intravenous (not otherwise specified)	560.0 Milligram	1 every 4 Weeks	150.0 Days	Rheumatoid arthritis
ACTEMRA	Suspect	Solution for infusion	Intravenous (not otherwise specified)	328.0 Milligram	1 every 4 Weeks	39.0 Days	Rheumatoid arthritis

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown			1.0 Days	Product used for unknown indication
METHOTREXATE	Concomitant	NOT SPECIFIED	Subcutaneous	25.0 Milligram	1 every 1 Weeks		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Postmenopausal haemorrhage	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04273087	1	2021-06-09	2021-08-20	MAH	2021634138	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
43 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Diarrhoea	v.24.1	
Flushing	v.24.1	9 Hours
Heart rate irregular	v.24.1	9 Hours
Heavy menstrual bleeding	v.24.1	
Menstrual disorder	v.24.1	
Nausea	v.24.1	9 Hours

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Panic attack	v.24.1	
Thrombosis	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04273136	2	2021-06-09	2021-07-26	MAH	2021606924	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
60 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Joint swelling	v.24.1	
Mobility decreased	v.24.1	
Pain in extremity	v.24.1	
Tendonitis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04273659	0	2021-06-10	2021-06-10	MAH	MOD-2021-193402	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
49 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ATIVAN	Concomitant	NOT SPECIFIED	Unknown	1.0 Dosage forms			Product used for unknown indication
CLARITIN [LORATADINE]	Concomitant		Unknown	1.0 Dosage forms			Product used for unknown indication
CLONAZEPAM	Concomitant	Tablets	Unknown	1.0 Dosage forms			Product used for unknown indication
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	1.0 Dosage forms			COVID-19 immunisation

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
HOMEOPATICS NOS	Concomitant		Unknown	1.0 Dosage forms			Product used for unknown indication
HYDROXYZINE	Concomitant		Unknown	1.0 Dosage forms			Product used for unknown indication
OLANZAPINE	Concomitant	NOT SPECIFIED	Unknown	1.0 Dosage forms			Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Angina pectoris	v.24.1	
Anxiety	v.24.1	
Disorientation	v.24.1	
Dizziness	v.24.1	
Mental disorder	v.24.1	
Nausea	v.24.1	
Panic attack	v.24.1	
Paraesthesia	v.24.1	
Paranoia	v.24.1	
Tremor	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04273686	1	2021-06-10	2021-08-05	MAH	CA2021AMR123286	Study	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
70 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_04835255
Linked	E2B_04835255

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				COVID-19 prophylaxis
MEPOLIZUMAB	Suspect	Powder for injection	Unknown	100.0 Milligram			Asthma
MEPOLIZUMAB	Suspect		Subcutaneous	100.0 Milligram			Asthma

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dyspnoea	v.24.1	
Oxygen therapy	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04275869	0	2021-06-10	2021-06-10	MAH	20210603320	Study	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
56 Years	Female		75 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				COVID-19 prophylaxis
REMICADE	Suspect	POWDER FOR SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	600.0 Milligram	1 every 6 Weeks		Rheumatoid arthritis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bronchitis	v.24.1	2 Months
Off label use	v.24.1	
Pneumonia	v.24.1	2 Months
Product use issue	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04277111	0	2021-06-10	2021-06-10	MAH	2021619081	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
79 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
RAMIPRIL	Concomitant	NOT SPECIFIED	Oral				Hypertension

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	1 Days
Breast pain	v.24.1	78 Days
Electric shock sensation	v.24.1	21 Days
Joint swelling	v.24.1	21 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04277128	2	2021-06-10	2021-07-26	MAH	2021612249	Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
23 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood pressure increased	v.24.1	
Chest discomfort	v.24.1	
Heart rate increased	v.24.1	
Heart rate irregular	v.24.1	
Hypoaesthesia	v.24.1	
Myocarditis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04277175	1	2021-06-10	2021-06-11	MAH	2021676970	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_04253369
Linked	E2B_04253369
Linked	E2B_04253369
Linked	E2B_04253369
Linked	E2B_04253369
Linked	E2B_04253369

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Drug ineffective	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04277205	1	2021-06-10	2021-06-11	MAH	2021676976	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_04253369
Linked	E2B_04253369
Linked	E2B_04253369
Linked	E2B_04253369
Linked	E2B_04253369
Linked	E2B_04253369

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Drug ineffective	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04277212	1	2021-06-10	2021-07-26	MAH	2021630489	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
32 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
DESOGESTREL/ETHINYL ESTRADIOL	Concomitant						
ESCITALOPRAM	Concomitant	Tablets					
MIRTAZAPINE	Concomitant	Tablets					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
TRANEXAMIC ACID	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Inappropriate schedule of product administration	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Muscle spasms	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04277231	0	2021-06-10	2021-06-10	MAH	2021629275	Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
22 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Syncope	v.24.1	0 Months

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04277240	2	2021-06-10	2021-06-28	MAH	2021613018	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
31 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
NAPROXEN	Concomitant	NOT SPECIFIED					
PANTOLOC [PANTOPRAZOLE]	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
QUETIAPINE FUMARATE	Concomitant						
VENLAFAXINE HYDROCHLORIDE	Concomitant						
VENTOLIN [SALBUTAMOL]	Concomitant						
ZOFRAN [ONDANSETRON]	Concomitant						Vomiting

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Constipation	v.24.1	
Dyspnoea exertional	v.24.1	
Fatigue	v.24.1	
Lymph node pain	v.24.1	
Lymphadenopathy	v.24.1	141 Hours
Nausea	v.24.1	
Vaccination site pain	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04277412	1	2021-06-10	2021-06-11	MAH	2021676975	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_04253369
Linked	E2B_04253369
Linked	E2B_04253369
Linked	E2B_04253369
Linked	E2B_04253369
Linked	E2B_04253369

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Drug ineffective	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04277419	1	2021-06-10	2021-06-11	MAH	2021676978	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_04253369
Linked	E2B_04253369
Linked	E2B_04253369
Linked	E2B_04253369
Linked	E2B_04253369
Linked	E2B_04253369

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Drug ineffective	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04277424	1	2021-06-10	2021-06-11	MAH	2021676972	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_04253369
Linked	E2B_04253369
Linked	E2B_04253369
Linked	E2B_04253369
Linked	E2B_04253369
Linked	E2B_04253369

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Drug ineffective	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04277432	1	2021-06-10	2021-06-11	MAH	2021676974	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_04253369
Linked	E2B_04253369
Linked	E2B_04253369
Linked	E2B_04253369
Linked	E2B_04253369
Linked	E2B_04253369

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Drug ineffective	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04277436	1	2021-06-10	2021-06-11	MAH	2021676503	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_04253369
Linked	E2B_04253369
Linked	E2B_04253369
Linked	E2B_04253369
Linked	E2B_04253369
Linked	E2B_04253369

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Drug ineffective	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04277462	1	2021-06-10	2021-06-11	MAH	2021676977	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_04253369
Linked	E2B_04253369
Linked	E2B_04253369
Linked	E2B_04253369
Linked	E2B_04253369
Linked	E2B_04253369

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Drug ineffective	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04277622	0	2021-06-10	2021-06-10	MAH	2021641516	Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown				COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04277743	1	2021-06-10	2021-07-26	MAH	2021612210	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
51 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AMITRIPTYLINE	Concomitant						
CLONAZEPAM	Concomitant	Tablets					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
PROPRANOLOL	Concomitant						
TRAMACET	Concomitant	Tablets					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest discomfort	v.24.1	0 Months
Dizziness	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hyperhidrosis	v.24.1	0 Months
Nausea	v.24.1	0 Months
Pain in extremity	v.24.1	0 Months
Vertigo positional	v.24.1	0 Months

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04277801	0	2021-06-10	2021-06-10	MAH	2021650399	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
43 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
EPINEPHRINE	Concomitant	NOT SPECIFIED	Intramuscular				Drug hypersensitivity
HYDROCHLOROTHIAZIDE	Concomitant	Tablets	Oral				Hypertension
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
ROSUVASTATIN CALCIUM	Concomitant		Oral				Blood cholesterol increased
TECTA	Concomitant	NOT SPECIFIED	Oral				Gastrooesophageal reflux disease

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bell's palsy	v.24.1	
Burning sensation	v.24.1	
Dyspnoea	v.24.1	
Facial pain	v.24.1	
Fatigue	v.24.1	
Otitis externa	v.24.1	
Pain	v.24.1	
Paraesthesia	v.24.1	-142
Peripheral swelling	v.24.1	-142
Vertigo	v.24.1	2 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04278079	0	2021-06-10	2021-06-10	MAH	2021640827	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
69 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BUDESONIDE/FORMOTEROL FUMARATE	Concomitant		Oral				Asthma
CANDESARTAN	Concomitant		Oral	8.0 Milligram	1 every 1 Days		Hypertension
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
ROSUVASTATIN	Concomitant	NOT SPECIFIED	Oral	10.0 Milligram	1 every 1 Days		Hypertension
SDZ CELECOXIB	Concomitant	Capsules	Oral				Hypertension
SINGULAIR	Concomitant	NOT SPECIFIED	Oral				Asthma
VENTOLIN [SALBUTAMOL SULFATE]	Concomitant		Oral				Asthma
WARFARIN	Concomitant		Oral				Thrombosis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal discomfort	v.24.1	
Frequent bowel movements	v.24.1	1 Days
Gastric haemorrhage	v.24.1	1 Days
Haematochezia	v.24.1	1 Days
Heart rate increased	v.24.1	30 Minutes

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04278081	1	2021-06-10	2021-06-11	MAH	2021676973	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_04253369
Linked	E2B_04253369
Linked	E2B_04253369
Linked	E2B_04253369
Linked	E2B_04253369
Linked	E2B_04253369

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Drug ineffective	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04278103	1	2021-06-10	2021-06-11	MAH	2021676971	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_04253369
Linked	E2B_04253369
Linked	E2B_04253369
Linked	E2B_04253369
Linked	E2B_04253369
Linked	E2B_04253369

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Drug ineffective	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04278188	1	2021-06-10	2021-07-22	MAH	2021649538	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
37 Years	Male		89 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
INFLIXIMAB	Suspect	NOT SPECIFIED	Intravenous (not otherwise specified)	5.0 mg/kg		16.0 Days	Colitis ulcerative
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood pressure fluctuation	v.24.1	
Colitis ulcerative	v.24.1	
Heart rate decreased	v.24.1	
Malaise	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04279516	1	2021-06-11	2021-09-01	MAH	2845599	Study	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
69 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETAMINOPHEN	Concomitant	NOT SPECIFIED	Oral	650.0 Milligram			Premedication
COVID-19 VACCINE	Suspect		Intramuscular			113.0 Days	Product used for unknown indication
DIPHENHYDRAMINE	Concomitant		Oral	50.0 Milligram			Premedication
METHYLPREDNISOLONE	Concomitant		Intravenous (not otherwise specified)	100.0 Milligram			Premedication
PREDNISONE	Concomitant	NOT SPECIFIED					
RITUXIMAB	Suspect		Intravenous (not otherwise specified)	500.0 Milligram	1 every 6 Months	5.0 Years	Microscopic polyangiitis
SEPTRA	Concomitant	Tablets					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cardiac disorder	v.24.1	
Dyspnoea	v.24.1	
Pericarditis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04279671	0	2021-06-11	2021-06-11	MAH	21K-028-3935266-00	Study	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
61 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular			1.0 Days	COVID-19 immunisation
COVID-19 VACCINE	Suspect		Intramuscular			0.0	COVID-19 immunisation
RINVOQ	Suspect	TABLET (EXTENDED-RELEASE)	Oral	15.0 Milligram	1 every 1 Days	2.0 Months	Rheumatoid arthritis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Drug ineffective	v.24.1	
Nausea	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04282241	0	2021-06-11	2021-06-11	MAH	2021630402	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
61 Years	Female			Recovered/resolved with sequelae

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CANDESARTAN	Concomitant			4.0 Milligram	every 1 Days		
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Burning sensation	v.24.1	
Chest discomfort	v.24.1	
Dyspnoea	v.24.1	
Heart rate increased	v.24.1	
Lip swelling	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pulmonary pain	v.24.1	
Sensory disturbance	v.24.1	
Swelling face	v.24.1	
Vaccination site movement impairment	v.24.1	
Vasodilatation	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04282257	1	2021-06-11	2021-06-16	MAH	2021640961	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
39 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
HYDROMORPHONE	Concomitant	NOT SPECIFIED					Pain
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.24.1	
Haematochezia	v.24.1	
Haematochezia	v.24.1	1 Days
Hot flush	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Rash	v.24.1	-146
Urticaria	v.24.1	-145

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04282284	1	2021-06-11	2021-07-19	MAH	2021619262	Spontaneous	Other health professional

Serious report?	Death:	Disability:	Congenital Anomaly:
Serious	Yes	No	No
	Life Threatening: No	**Hospitalization:** No	**Other Medically Important Conditions:** Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Fatal

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_04253369
Linked	E2B_04253369
Linked	E2B_04253369
Linked	E2B_04253369
Linked	E2B_04253369
Linked	E2B_04253369

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Drug ineffective	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Gastrointestinal haemorrhage	v.24.1	
SARS-CoV-2 test positive	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04282294	1	2021-06-11	2021-07-23	MAH	2021619526	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
51 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CLARITIN [LORATADINE]	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
PROBIOTICS NOS	Concomitant						
SELENIUM	Concomitant	NOT SPECIFIED					
VITAMIN B12	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.24.1	
Hyperhidrosis	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypertension	v.24.1	
Malaise	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04282345	1	2021-06-11	2021-08-09	MAH	2021618420	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
64 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AMLODIPINE	Concomitant	Tablets	Oral	5.0 Milligram			Hypertension
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pericarditis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04282352	1	2021-06-11	2021-06-15	MAH	2021654635	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
72 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CONSTELLA	Concomitant	Capsules					Constipation
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
PRUCALOPRIDE SUCCINATE	Concomitant						Constipation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Heart rate increased	v.24.1	1 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04282378	1	2021-06-11	2021-07-26	MAH	2021629425	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
13 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.24.1	
Fatigue	v.24.1	
Nausea	v.24.1	
Syncope	v.24.1	
Visual impairment	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04282381	0	2021-06-11	2021-06-11	MAH	2021619067	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
21 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Asthenia	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Lymphadenopathy	v.24.1	
Myalgia	v.24.1	
Off label use	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pyrexia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04282555	1	2021-06-11	2021-07-26	MAH	2021620437	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
31 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Loss of consciousness	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04282557	1	2021-06-11	2021-07-26	MAH	2021619178	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
42 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Months	COVID-19 immunisation
SULFASALAZINE	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pericarditis	v.24.1	
Pleurisy	v.24.1	
Rheumatoid arthritis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04282576	0	2021-06-11	2021-06-11	MAH	2021618508	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
54 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ALOXIPRIN	Concomitant						
BUPROPION	Concomitant						
MESALAMINE	Concomitant	NOT SPECIFIED					
NABILONE	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
TRAMADOL	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain upper	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Colitis	v.24.1	
Diarrhoea	v.24.1	
Haematochezia	v.24.1	
Nausea	v.24.1	
Purulent discharge	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04282589	0	2021-06-11	2021-06-11	MAH	2021618071	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
76 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
RAMIPRIL	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood pressure increased	v.24.1	
Dyspnoea	v.24.1	
Fatigue	v.24.1	
Heart rate decreased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04282661	2	2021-06-11	2021-08-19	MAH	2021619813	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_04253369
Linked	E2B_04253369
Linked	E2B_04253369
Linked	E2B_04253369
Linked	E2B_04253369
Linked	E2B_04253369
Linked	E2B_04253369

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04283115	1	2021-06-11	2021-07-13	MAH	2021372326	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
72 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CITALOPRAM	Concomitant			20.0 Milligram			
COPPER CITRATE/D-ALPHA TOCOPHERYL ACETATE/VITAMIN C/XANTOFYL PALMITATE/ZEAXANTHIN/ ZINC OXIDE	Concomitant						
GLUCOSAMINE	Concomitant	NOT SPECIFIED					
PANTOPRAZOL [PANTOPRAZOLE]	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.24.1	3 Months
Cold sweat	v.24.1	
Cough	v.24.1	
Dizziness	v.24.1	
Dyspnoea	v.24.1	
Fatigue	v.24.1	
Fatigue	v.24.1	
Headache	v.24.1	
Malaise	v.24.1	
Nausea	v.24.1	
Oropharyngeal pain	v.24.1	
Peripheral swelling	v.24.1	
Pneumonia	v.24.1	
Pruritus	v.24.1	
Rash erythematous	v.24.1	
Rhinorrhoea	v.24.1	
Throat tightness	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04283287	2	2021-06-11	2021-07-13	MAH	2021630589	Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
41 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MAXALT	Concomitant	Tablets	Sublingual				Migraine
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Migraine	v.24.1	3 Days
Ophthalmic herpes zoster	v.24.1	160 Hours

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04283314	1	2021-06-11	2021-08-03	MAH	2021621131	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
39 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Skin discolouration	v.24.1	
Skin exfoliation	v.24.1	
Vaccination site erythema	v.24.1	
Vaccination site induration	v.24.1	
Vaccination site swelling	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04283714	1	2021-06-11	2021-08-03	MAH	2021504828	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
74 Years	Male	173 Centimeter		Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Duplicate	E2B_04111968

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AMLODIPINE	Concomitant	Tablets	Oral		every 1 Days		Hypertension
ELIQUIS FILM COATED	Suspect	Tablets	Oral	5.0 Milligram	2 every 1 Days		Cerebrovascular accident prophylaxis, COVID-19 prophylaxis
ELIQUIS FILM COATED	Suspect	Film-coated tablet	Unknown				Cerebrovascular accident prophylaxis, COVID-19 prophylaxis
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04283851	0	2021-06-11	2021-06-11	MAH	2848081	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				Product used for unknown indication
OCRELIZUMAB	Suspect		Intravenous (not otherwise specified)	300.0 Milligram			Relapsing-remitting multiple sclerosis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cellulitis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04284234	1	2021-06-12	2021-06-14	MAH	21K-028-3937325-00	Study	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
46 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular			1.0 Months	COVID-19 immunisation
HUMIRA	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous	40.0 Milligram	1 every 2 Weeks		Rheumatoid arthritis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Gait disturbance	v.24.1	
Rheumatoid arthritis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04284335	1	2021-06-12	2021-06-28	MAH	2021622598	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
61 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MAGNESIUM	Concomitant	NOT SPECIFIED		250.0 Milligram	1 every 1 Days		Nephrolithiasis
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Angina pectoris	v.24.1	
Arthralgia	v.24.1	
Ear pain	v.24.1	
Headache	v.24.1	16 Days
Muscle spasms	v.24.1	21 Days

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Myalgia	v.24.1	
Vaccination site pain	v.24.1	21 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04284850	5	2021-06-13	2021-10-25	MAH	2848399	Study	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
80 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				Immunisation
ESBRIET	Suspect	Tablet	Oral	801.0 Milligram	3 every 1 Days	47.0 Days	Idiopathic pulmonary fibrosis
ESBRIET	Suspect	Tablet	Oral		1 every 1 Days	-3.0	Idiopathic pulmonary fibrosis

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ESBRIET	Suspect	Tablet	Oral	534.0 Milligram	3 every 1 Days	152.0 Days	Idiopathic pulmonary fibrosis
ESBRIET	Suspect	Tablet	Oral	534.0 Milligram	3 every 1 Days	1.0 Months	Idiopathic pulmonary fibrosis
ESBRIET	Suspect	Tablet	Oral	267.0 Milligram	3 every 1 Days	0.0 Months	Idiopathic pulmonary fibrosis
IRBESARTAN	Concomitant	Tablets	Unknown				Product used for unknown indication
PLANTAGO OVATA	Concomitant						Product used for unknown indication
RABEPRAZOLE	Concomitant						Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain upper	v.24.1	
Blood sodium decreased	v.24.1	1 Days
Dehydration	v.24.1	
Gastrointestinal pain	v.24.1	
Intentional dose omission	v.24.1	
Nausea	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04285024	0	2021-06-13	2021-06-13	MAH	2021622775	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
82 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation
RABEPRAZOLE	Concomitant						
SYNTHROID	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Decreased appetite	v.24.1	
Dehydration	v.24.1	
Diarrhoea	v.24.1	
Fatigue	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypotension	v.24.1	
Muscular weakness	v.24.1	
Pyrexia	v.24.1	
Syncope	v.24.1	
Weight decreased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04285882	0	2021-06-14	2021-06-14	MAH	CA2021AMR102648	Study	Other health professional

Serious report?	Death:	Disability:	Congenital Anomaly:
Serious	Yes	No	No
	Life Threatening: No	**Hospitalization:** No	**Other Medically Important Conditions:** Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
52 Years	Male			Fatal

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_04022832
Linked	
Linked	
Linked	
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MEPOLIZUMAB	Suspect		Subcutaneous	100.0 Milligram		615.0 Days	Asthma
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				COVID-19 prophylaxis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Death	v.24.1	1 Months

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Injection related reaction	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04286027	0	2021-06-14	2021-06-14	MAH	CA2021AMR059467	Study	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
70 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	
Linked	E2B_01588052
Linked	E2B_01914676
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	E2B_03019128
Linked	E2B_05068164
Linked	
Linked	
Linked	E2B_05068164

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BUDESONIDE/FORMOTEROL FUMARATE	Suspect		Unknown				Product used for unknown indication
COVID-19 VACCINE	Suspect		Unknown				Product used for unknown indication
MEPOLIZUMAB	Suspect		Subcutaneous	100.0 Milligram			Product used for unknown indication, Asthma
MEPOLIZUMAB	Suspect	Powder for injection	Subcutaneous	100.0 Milligram			Product used for unknown indication, Asthma
NAPROXEN	Suspect	NOT SPECIFIED	Unknown				Product used for unknown indication
OMALIZUMAB	Suspect	NOT SPECIFIED	Unknown				Product used for unknown indication
PROMETRIUM	Suspect	Capsules	Unknown				Product used for unknown indication
SINGULAIR	Suspect	NOT SPECIFIED	Unknown				Product used for unknown indication
SPIRIVA	Suspect	NOT SPECIFIED	Unknown				Product used for unknown indication
SYNTHROID	Suspect	NOT SPECIFIED	Unknown				Product used for unknown indication
VENLAFAXINE HYDROCHLORIDE	Suspect		Unknown				Product used for unknown indication
VENTOLIN	Suspect	NOT SPECIFIED	Unknown				Product used for unknown indication
VITAMIN D	Suspect	NOT SPECIFIED	Unknown				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Back pain	v.24.1	
Ear infection	v.24.1	
Fatigue	v.24.1	
Musculoskeletal chest pain	v.24.1	
Nerve compression	v.24.1	
Oropharyngeal pain	v.24.1	
Sinusitis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04287836	2	2021-06-14	2021-07-23	MAH	2021633973	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
16 Years	Male	180 Centimeter	113 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Confusional state	v.24.1	
Hallucination	v.24.1	
Memory impairment	v.24.1	
Mental disorder	v.24.1	
Psychotic disorder	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04287912	2	2021-06-14	2021-07-26	MAH	2021634385	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
52 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Crying	v.24.1	
Depressed mood	v.24.1	
Heavy menstrual bleeding	v.24.1	
Suicidal ideation	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04288059	1	2021-06-14	2021-06-15	MAH	2021629072	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
56 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Deafness unilateral	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04288183	1	2021-06-14	2021-09-14	MAH	2021630152	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
16 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Confusional state	v.24.1	
Paranoia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04288402	1	2021-06-14	2021-07-26	MAH	2021629800	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
59 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
B12 [CYANOCOBALAMIN]	Concomitant						
COVERSYL [PERINDOPRIL ERBUMINE]	Concomitant			4.0 Milligram			
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
VIAGRA [SILDENAFIL]	Concomitant				As required		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Retinal vein occlusion	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04288575	0	2021-06-14	2021-06-14	MAH	2021650502	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
29 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest discomfort	v.24.1	
Dyspnoea	v.24.1	
Eye pruritus	v.24.1	
Fatigue	v.24.1	
Hypersensitivity	v.24.1	
Insomnia	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Nasal pruritus	v.24.1	
Rhinorrhoea	v.24.1	
Swelling face	v.24.1	1 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04288680	1	2021-06-14	2021-07-28	MAH	2021630533	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
36 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cardiac flutter	v.24.1	6 Days
Dizziness	v.24.1	2 Days
Dysmenorrhoea	v.24.1	0 Months
Fatigue	v.24.1	8 Days
Feeling abnormal	v.24.1	8 Days
Feeling hot	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Heavy menstrual bleeding	v.24.1	0 Months
Hypotension	v.24.1	3 Days
Nausea	v.24.1	13 Days
Paraesthesia	v.24.1	
Polymenorrhoea	v.24.1	0 Months

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04291508	1	2021-06-15	2021-06-30	MAH	MOD-2021-211340	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
73 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	Injection	Unknown	1.0 Dosage forms			COVID-19 immunisation
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	1.0 Dosage forms			COVID-19 immunisation
PREDNISONE	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Immune system disorder	v.24.1	1 Months

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04293011	1	2021-06-15	2021-06-25	MAH	2021629586	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
61 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Concussion	v.24.1	
Contusion	v.24.1	
Fall	v.24.1	
Post-traumatic neck syndrome	v.24.1	
Syncope	v.24.1	-146

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04293088	1	2021-06-15	2021-06-16	MAH	2021654726	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cardiac disorder	v.24.1	
Chest pain	v.24.1	
Dyspnoea	v.24.1	
Thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:02:01 AM
Initial Received Date:	2021-05-01 to 2021-06-15
Latest Received Date:	N/A
Total Number of Reports:	751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04293147	1	2021-06-15	2021-09-15	MAH	2021633864	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
32 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown			1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chromatopsia	v.24.1	
Eye pain	v.24.1	
Optic neuritis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04293297	1	2021-06-15	2021-07-28	MAH	2021634249	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
29 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Months	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Facial paralysis	v.24.1	0
Headache	v.24.1	0

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04293311	1	2021-06-15	2021-07-29	MAH	2021634716	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
78 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Ocular vascular disorder	v.24.1	
Retinal artery occlusion	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04293332	2	2021-06-15	2021-07-28	MAH	2021635675	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
37 Years	Female	168 Centimeter	176 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abortion spontaneous	v.24.1	-126
Haemorrhage	v.24.1	-126
Pain	v.24.1	-126
Uterine contractions abnormal	v.24.1	-126

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04293364	0	2021-06-15	2021-06-15	MAH	2021640085	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
37 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Burning sensation	v.24.1	
Dysgeusia	v.24.1	1 Weeks
Fatigue	v.24.1	
Feeling abnormal	v.24.1	
Myalgia	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Nausea	v.24.1	
Neck pain	v.24.1	
Pain in extremity	v.24.1	
Pyrexia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04293516	1	2021-06-15	2021-06-28	MAH	2021654720	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
94 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Blister	v.24.1	
Dry mouth	v.24.1	
Herpes zoster	v.24.1	
Insomnia	v.24.1	
Pain in extremity	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Weight decreased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:02:01 AM
Initial Received Date: 2021-05-01 to 2021-06-15
Latest Received Date: N/A
Total Number of Reports: 751 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04293751	1	2021-06-15	2021-06-29	MAH	2021612938	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blister	v.24.1	
Feeling abnormal	v.24.1	
Pain	v.24.1	
Rash	v.24.1	

Health Canada Santé Canada

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:07:47 AM
Initial Received Date:	2021-06-16 to 2021-07-30
Latest Received Date:	N/A
Total Number of Reports:	802 Report(s)

Brand Name/Active Ingredient: covid
Search Date Criteria: 2021-06-16 to 2021-07-30
Reaction Term(s): All/Tous
Serious report?: Both
Type of Report: All
Source of Report: All
Gender: All
Report Outcome: All
Age: All

CAVEAT: This summary is based on information from adverse reaction reports submitted by health professionals and laypersons either directly to Health Canada or via market authorization holders. Each report represents the suspicion, opinion or observation of the individual reporter. The Canada Vigilance Program is a spontaneous reporting system that is suitable to detect signals of potential health product safety issues during the post-market period. The data has been collected primarily by a spontaneous surveillance system in which adverse reactions to health products are reported on a voluntary basis. Under reporting of adverse reactions is seen with both voluntary and mandatory spontaneous surveillance systems. Accumulated case reports should not be used as a basis for determining the incidence of a reaction or estimating risk for a particular product as neither the total number of reactions occurring, nor the number of patients exposed to the health product is known. Because of the multiple factors that influence reporting, quantitative comparisons of health product safety cannot be made from the data. Some of these factors include the length of time a drug is marketed, the market share, size and sophistication of the sales force, publicity about an adverse reaction and regulatory actions. In some cases, the reported clinical data is incomplete and there is not certainty that these health products caused the reported reactions. A given reaction may be due to an underlying disease process or to another coincidental factor. This information is provided with the understanding that the data will be appropriately referenced and used in conjunction with this caveat statement.

Canada

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000954668	0	2021-06-16	2021-06-16	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
60 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dysphonia	v.24.1	
Flushing	v.24.1	
Paraesthesia	v.24.1	
Tachycardia	v.24.1	
Tachypnoea	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000954673	0	2021-06-16	2021-06-16	Hospital		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
21 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ADVIL IBUPROFEN TAB 200MG	Concomitant	Tablets					
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	0.5 ml	Once		COVID-19 prophylaxis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.24.1	
Myocarditis	v.24.1	
Nausea	v.24.1	
Troponin increased	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000954675	0	2021-06-16	2021-06-16	Community		Spontaneous	Pharmacist

Serious report?	Death:		Disability:		Congenital Anomaly:	
Not Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	

Patient Information

Age	Gender	Height	Weight	Report Outcome
26 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	0.5 ml			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Diarrhoea	v.24.1	
Dizziness	v.24.1	
Hyperhidrosis	v.24.1	
Pyrexia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000954677	0	2021-06-16	2021-06-16	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	Disability:	Congenital Anomaly:
Serious	Yes	No	No
	Life Threatening: No	**Hospitalization:** No	**Other Medically Important Conditions:** No

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Fatal

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dyspnoea	v.24.1	
Lung disorder	v.24.1	
Oxygen saturation decreased	v.24.1	
Oxygen therapy	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000954867	0	2021-06-17	2021-06-17	Hospital		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
56 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID VACCINE	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				
MAXALT	Concomitant	Tablets					
MOMETASONE FUROATE	Concomitant	NOT SPECIFIED					
NAPROXEN	Concomitant	NOT SPECIFIED					
OMNARIS	Concomitant	SPRAY, METERED DOSE					
VIAGRA	Concomitant	Tablets					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Feeling abnormal	v.24.1	
Headache	v.24.1	
Hypoaesthesia	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Paraesthesia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000954869	0	2021-06-17	2021-06-17	Hospital		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
25 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml			COVID-19 immunisation
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Myocarditis	v.24.1	
Palpitations	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000954882	0	2021-06-17	2021-06-17	Hospital		Spontaneous	Physician

Serious report?	Death:	Yes	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
79 Years	Male		406 Pound	Fatal

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cellulitis	v.24.1	6 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000954886	0	2021-06-17	2021-06-17	Hospital		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
72 Years	Female		52 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ALLOPURINOL	Concomitant	Tablets					
APIDRA	Concomitant	SOLUTION SUBCUTANEOUS					
CANDESARTAN	Concomitant						
ESCITALOPRAM	Concomitant	Tablets					
HYDROCHLOROTHIAZIDE	Concomitant	Tablets					
INSULIN GLARGINE	Concomitant	SOLUTION SUBCUTANEOUS					
LEVODOPA-CARBIDOPA	Concomitant	Tablets					
METOCLOPRAMIDE	Concomitant	NOT SPECIFIED					
NIFEDIPINE	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular			80.0 Days	
POTASSIUM CHLORIDE	Concomitant	NOT SPECIFIED					

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
QUETIAPINE	Concomitant	Tablets					
ROSUVASTATIN	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Deep vein thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000954897	0	2021-06-17	2021-06-17	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
41 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Once		Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Vestibular disorder	v.24.1	
Vestibular neuronitis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000955046	0	2021-06-20	2021-06-20	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
37 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				
SYNTHROID	Concomitant	NOT SPECIFIED					
VENTOLIN	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Loss of personal independence in daily activities	v.24.1	
Pain	v.24.1	
Vaccination site movement impairment	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000955049	0	2021-06-18	2021-06-18	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
79 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR		0.3 ml	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Bedridden	v.24.1	
Fatigue	v.24.1	
Paralysis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000955050	0	2021-06-20	2021-06-20	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
31 Years	Male	185 Centimeter	78 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Lymphadenopathy	v.24.1	
Myalgia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000955051	0	2021-06-18	2021-06-18	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
22 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Body temperature increased	v.24.1	
Chest discomfort	v.24.1	
Chills	v.24.1	
Dyspnoea	v.24.1	
Fibrin D dimer increased	v.24.1	
Oropharyngeal pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000955052	0	2021-06-18	2021-06-18	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
76 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PERINDOPRIL	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR					COVID-19

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.24.1	
Dizziness postural	v.24.1	
Ear discomfort	v.24.1	
Feeling abnormal	v.24.1	
Vertigo	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000955053	0	2021-06-19	2021-06-19	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
51 Years		168 Centimeter	76 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CIPRALEX	Concomitant	Tablets					
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular		Once		Immunisation
MELATONIN	Concomitant	NOT SPECIFIED					
STALEVO	Concomitant	Tablets					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.24.1	
Headache	v.24.1	
Myalgia	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Nausea	v.24.1	
Pyrexia	v.24.1	
Vaccination site erythema	v.24.1	
Vaccination site pruritus	v.24.1	
Vaccination site rash	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000955056	0	2021-06-18	2021-06-18	Hospital		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
54 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID VACCINE	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.5 ml		45.0 Days	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Guillain-Barre syndrome	v.24.1	31 Days
Mechanical ventilation	v.24.1	
Paraesthesia	v.24.1	
Respiratory failure	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000955057	0	2021-06-18	2021-06-18	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
18 Years	Male		48 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ADVIL	Concomitant	NOT SPECIFIED					
BENADRYL	Concomitant	Capsules					
MINOCIN	Concomitant	Capsules					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		
SALINEX	Concomitant						
ZITHROMAX	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Injection site erythema	v.24.1	
Injection site pain	v.24.1	
Injection site pruritus	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Injection site warmth	v.24.1	
Rash	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:07:47 AM
Initial Received Date:	2021-06-16 to 2021-07-30
Latest Received Date:	N/A
Total Number of Reports:	802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000955059	0	2021-06-18	2021-06-18	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
29 Years	Male	68 Inch	138 Pound	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		COVID-19 prophylaxis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Injection site pain	v.24.1	
Neck pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000955060	0	2021-06-20	2021-06-20	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
51 Years	Female	165 Centimeter		Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Subcutaneous		Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Back pain	v.24.1	
Headache	v.24.1	
Hypersensitivity	v.24.1	
Lymphadenopathy	v.24.1	
Meningitis aseptic	v.24.1	
Musculoskeletal stiffness	v.24.1	
Neck pain	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pyrexia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000955062	0	2021-06-19	2021-06-19	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
45 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Once		COVID-19 prophylaxis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Hot flush	v.24.1	
Hyperhidrosis	v.24.1	
Joint swelling	v.24.1	
Lethargy	v.24.1	
Pain in extremity	v.24.1	3 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000955063	0	2021-06-18	2021-06-18	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
76 Years	Female		67 Pound	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ATIVAN	Concomitant	NOT SPECIFIED					
HYDROCHLOROTHIAZIDE	Concomitant	Tablets					
PARIET	Concomitant	TABLET (ENTERIC-COATED)					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR			Once		
RAMIPRIL	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Migraine	v.24.1	
Tension headache	v.24.1	
Visual impairment	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000955065	0	2021-06-18	2021-06-18	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
51 Years	Male	76 Inch	122 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ANTIINFECTIVES FOR SYSTEMIC USE	Concomitant	NOT SPECIFIED					
ASTRAZENECA COVID VACCINE	Suspect	SOLUTION INTRAMUSCULAR		0.5 ml	Once		COVID-19

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Peripheral swelling	v.24.1	
Thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000955066	0	2021-06-20	2021-06-20	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					
XARELTO	Concomitant	Coated tablet					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anxiety	v.24.1	
Deep vein thrombosis	v.24.1	
Fatigue	v.24.1	
Impaired quality of life	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000955067	1	2021-06-18	2021-06-30	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
63 Years	Male	72 Inch	185 Pound	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID VACCINE	Suspect	SOLUTION INTRAMUSCULAR					
TAMSULOSIN	Suspect	NOT SPECIFIED	Oral				Prostatomegaly
VITAMIN D	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Back pain	v.24.1	
Impaired quality of life	v.24.1	
Inflammation	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000955068	0	2021-06-18	2021-06-18	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR			Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Diarrhoea	v.24.1	
Nausea	v.24.1	
Swollen tongue	v.24.1	
Throat tightness	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000955074	0	2021-06-18	2021-06-18	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
58 Years	Female	156 Centimeter	56 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BETAMETHASONE	Concomitant	NOT SPECIFIED					
BIAXIN	Concomitant	NOT SPECIFIED					
BREO ELLIPTA	Concomitant	INHALATION					
CANDESARTAN	Concomitant						
GABAPENTIN	Concomitant	NOT SPECIFIED					
GLUCAGON	Concomitant	KIT					
INSTA-GLUCOSE	Concomitant	LIQUID ORAL					
IRON	Concomitant	NOT SPECIFIED					
NOVORAPID FLEXTOUCH - PREFILLED MULTIDOSE DISPOSABLE INSULIN DELIVERY DEVICE CONTAINING A 3ML CARTRIDGE	Concomitant	SOLUTION SUBCUTANEOUS					

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				COVID-19 prophylaxis
PREVACID	Concomitant	NOT SPECIFIED					
REACTINE	Concomitant	NOT SPECIFIED					
VAGIFEM	Concomitant	Vaginal suppository					
VENTOLIN	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Erythema multiforme	v.24.1	21 Days
Rash erythematous	v.24.1	
Rash pruritic	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000955236	0	2021-06-21	2021-06-21	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
46 Years	Male	175 Centimeter	77 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.24.1	13 Days
Dyspnoea	v.24.1	
Malaise	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000955237	0	2021-06-21	2021-06-21	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
45 Years	Female			Recovering/resolving

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.24.1	
Dizziness	v.24.1	
Feeling hot	v.24.1	
Nausea	v.24.1	
Pain in extremity	v.24.1	
Vaccination site pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000955239	0	2021-06-21	2021-06-21	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
48 Years	Female	153 Centimeter	49 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID VACCINE	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	1.0 Dosage forms	Once		COVID-19 prophylaxis
PANTOLOC	Concomitant	TABLET (ENTERIC-COATED)					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.24.1	
Dyspnoea	v.24.1	
Fatigue	v.24.1	
Myocarditis	v.24.1	
Pericarditis	v.24.1	47 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000955240	0	2021-06-21	2021-06-21	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
41 Years	Female	155 Centimeter	64 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Other		Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Eyelids pruritus	v.24.1	
Herpes zoster	v.24.1	
Hypoaesthesia	v.24.1	
Neuralgia	v.24.1	
Pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000955246	0	2021-06-21	2021-06-21	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
29 Years				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect				Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.24.1	
Dysphagia	v.24.1	
Dyspnoea	v.24.1	
Palpitations	v.24.1	
Pericarditis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000955247	0	2021-06-21	2021-06-21	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
KEFLEX	Concomitant	NOT SPECIFIED					
MELOXICAM	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Eye pain	v.24.1	
Swelling	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000955252	0	2021-06-21	2021-06-21	Community		Spontaneous	Physician

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
		70 Inch		Recovering/resolving

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASA	Concomitant	NOT SPECIFIED	Unknown				
AZATHIOPRINE	Concomitant	Tablets					
FLUOXETINE	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Deafness bilateral	v.24.1	
Ear pain	v.24.1	
Nausea	v.24.1	
Phonophobia	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Vertigo	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000955254	0	2021-06-21	2021-06-21	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect				Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Cough	v.24.1	
Disease progression	v.24.1	
Dyspnoea	v.24.1	
Fatigue	v.24.1	
Headache	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Increased upper airway secretion	v.24.1	
Influenza	v.24.1	
Myalgia	v.24.1	
Saliva discolouration	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000955255	0	2021-06-21	2021-06-21	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
75 Years	Male	170 Centimeter	82 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ARTHROTEC 50	Concomitant	TABLET (DELAYED-RELEASE)					
FLOMAX /01280302/	Concomitant						
LORAZEPAM	Concomitant	NOT SPECIFIED					
NORVASC	Concomitant	Tablets					
PARIET, ENTERIC-COATED TABLET 10MG	Concomitant	TABLET (ENTERIC-COATED)					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Once		COVID-19 immunisation
TRAZODONE	Concomitant	Tablets					
TRIAMTERENE & HYDROCHLOROTHIAZIDE	Concomitant	Tablets					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Rash follicular	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000955256	0	2021-06-21	2021-06-21	Community		Spontaneous	Physician

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
27 Years	Female			Recovering/resolving

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR			Once		Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Herpes zoster	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000955257	0	2021-06-21	2021-06-21	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Atrial fibrillation	v.24.1	
Fatigue	v.24.1	
Heart rate increased	v.24.1	
Pain in extremity	v.24.1	
Pruritus	v.24.1	
Rash	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Swelling	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000955506	0	2021-06-22	2021-06-22	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
55 Years	Female	160 Centimeter	72 Kilogram	Recovering/resolving

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
Desiccated Formula 90mg/ 25mg Zinc	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pruritus	v.24.1	
Urticaria	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000955508	1	2021-06-22	2021-08-14	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
37 Years	Female	62 Inch	190 Pound	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cognitive disorder	v.24.1	
Coordination abnormal	v.24.1	
Disorganised speech	v.24.1	
Disturbance in attention	v.24.1	
Dizziness	v.24.1	
Feeling abnormal	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Gait disturbance	v.24.1	
Hypersomnia	v.24.1	
Impaired driving ability	v.24.1	
Lethargy	v.24.1	
Memory impairment	v.24.1	
Nervous system disorder	v.24.1	
Vertigo	v.24.1	
Vision blurred	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000955512	0	2021-06-23	2021-06-23	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Unknown		Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Injection site erythema	v.24.1	
Injection site pain	v.24.1	
Injection site plaque	v.24.1	
Injection site swelling	v.24.1	
Injection site warmth	v.24.1	
Skin reaction	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000955513	0	2021-06-22	2021-06-22	Community		Spontaneous	Physician

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
56 Years	Female	153 Centimeter	77 Kilogram	Recovering/resolving

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cellulitis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000955516	0	2021-06-22	2021-06-22	Community		Spontaneous	Physician

Serious report?	Death:		Disability:		Congenital Anomaly:	
Not Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	

Patient Information

Age	Gender	Height	Weight	Report Outcome
70 Years	Male	175 Centimeter	96 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR			Once		COVID-19 immunisation
PREDNISONE	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blister	v.24.1	
Herpes zoster	v.24.1	
Pain	v.24.1	
Skin plaque	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000955518	0	2021-06-22	2021-06-22	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR			Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Myalgia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000955519	0	2021-06-22	2021-06-22	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
68 Years	Female	171 Centimeter	88 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect			0.5 ml			COVID-19 immunisation
CRESTOR	Concomitant	Tablets					
FLOVENT	Concomitant	NOT SPECIFIED					
TECTA	Concomitant	NOT SPECIFIED	Unknown				
VENTOLIN	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Asthenia	v.24.1	
Chills	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Diarrhoea	v.24.1	
Dyspnoea	v.24.1	
Myalgia	v.24.1	
Pyrexia	v.24.1	
SARS-CoV-2 test positive	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000955697	0	2021-06-23	2021-06-23	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
72 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
LIV MILIEU	Suspect	LIQUID ORAL		5.0 Drops	Once		Detoxification
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		COVID-19 prophylaxis
PRINIVIL	Concomitant	Tablets					
ZOPICLONE	Concomitant	Tablets					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Asthenia	v.24.1	
Dizziness	v.24.1	
Fatigue	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Feeling abnormal	v.24.1	
Myalgia	v.24.1	
Pain	v.24.1	
Sensitive skin	v.24.1	
Syncope	v.24.1	
Tremor	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000955698	0	2021-06-23	2021-06-23	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
26 Years	Female	185 Centimeter	77 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		COVID-19 immunisation
VENLAFAXINE XR	Concomitant	CAPSULE, EXTENDED RELEASE					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.24.1	5 Days
Cough	v.24.1	
Dyspnoea	v.24.1	
Fatigue	v.24.1	
Loss of consciousness	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Oropharyngeal pain	v.24.1	
Pain	v.24.1	
Painful respiration	v.24.1	
Syncope	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000955699	0	2021-06-23	2021-06-23	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
59 Years	Female	163 Centimeter	78 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Unknown				COVID-19

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cough	v.24.1	
Pain in extremity	v.24.1	
Vaccination site mass	v.24.1	
Vaccination site pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000955934	0	2021-06-24	2021-06-24	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
36 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intradermal	1.0 Dosage forms			COVID-19 immunisation
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Lymph node tuberculosis	v.24.1	
Swelling	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000955935	0	2021-06-24	2021-06-24	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
46 Years	Male			Recovering/resolving

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR		0.3 ml			COVID-19 immunisation
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain	v.24.1	
Arthralgia	v.24.1	
Confusional state	v.24.1	
Decreased appetite	v.24.1	
Depressed mood	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Diarrhoea	v.24.1	
Dizziness	v.24.1	
Dyschromatopsia	v.24.1	
Dysgeusia	v.24.1	
Dyspepsia	v.24.1	
Ear infection	v.24.1	
Ear pain	v.24.1	
Erythema	v.24.1	
Fatigue	v.24.1	
Headache	v.24.1	
Hyperacusis	v.24.1	
Hypotonia	v.24.1	
Impaired driving ability	v.24.1	
Inappropriate affect	v.24.1	
Jaw disorder	v.24.1	
Memory impairment	v.24.1	
Middle insomnia	v.24.1	
Mobility decreased	v.24.1	
Night sweats	v.24.1	
Nightmare	v.24.1	
Palpitations	v.24.1	
Photophobia	v.24.1	
Pressure of speech	v.24.1	
Rhinalgia	v.24.1	
Slow speech	v.24.1	
Stress	v.24.1	
Swelling	v.24.1	
Tinnitus	v.24.1	
Visual field defect	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000955939	0	2021-06-24	2021-06-24	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
28 Years	Female	67 Inch	272 Pound	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypersensitivity	v.24.1	
Pharyngeal swelling	v.24.1	
Upper respiratory tract congestion	v.24.1	
Vaccination site erythema	v.24.1	
Vaccination site paraesthesia	v.24.1	
Vaccination site swelling	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000955941	0	2021-06-24	2021-06-24	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
38 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR			Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anxiety	v.24.1	
Body temperature increased	v.24.1	
Chest pain	v.24.1	
Cognitive disorder	v.24.1	
Headache	v.24.1	
Palpitations	v.24.1	
Paraesthesia	v.24.1	
Vision blurred	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000955942	0	2021-06-24	2021-06-24	Community		Spontaneous	Physician

Serious report?	Death:		Disability:		Congenital Anomaly:	
Not Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	

Patient Information

Age	Gender	Height	Weight	Report Outcome
36 Years	Male	170 Centimeter	90 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		COVID-19 prophylaxis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anxiety	v.24.1	
Chest discomfort	v.24.1	1 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000955946	0	2021-06-24	2021-06-24	Hospital		Spontaneous	Physician

Serious report?	Death:		Disability:	Yes	Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	

Patient Information

Age	Gender	Height	Weight	Report Outcome
31 Years	Male	175 Centimeter	69 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	1.0 Dosage forms			COVID-19 immunisation
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	1.0 Dosage forms			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000955948	0	2021-06-24	2021-06-24	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
70 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect				Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pruritus	v.24.1	
Rash erythematous	v.24.1	
Rash papular	v.24.1	
Skin discharge	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000955949	0	2021-06-24	2021-06-24	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
65 Years				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR			Once	69.0 Days	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cataract	v.24.1	
Dizziness	v.24.1	
Vision blurred	v.24.1	
Visual impairment	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000955950	0	2021-06-24	2021-06-24	Hospital		Spontaneous	Physician

Serious report?	Death:		Disability:	Yes	Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	

Patient Information

Age	Gender	Height	Weight	Report Outcome
23 Years	Female	158 Centimeter	157 Pound	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	000955961

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ADVIL	Concomitant	NOT SPECIFIED					
CONCERTA	Concomitant	TABLET (EXTENDED-RELEASE)					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	1.0 Dosage forms	Once		COVID-19 immunisation
TYLENOL	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain	v.24.1	
Decreased appetite	v.24.1	
Gastritis	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Odynophagia	v.24.1	
Oesophagitis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000955954	0	2021-06-24	2021-06-24	Community		Spontaneous	Physician

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
78 Years	Female	166 Centimeter	81 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect			1.0 Dosage forms	Once		
CROMOLYN EYE DROPS	Concomitant	SOLUTION OPHTHALMIC					
PREMARIN	Concomitant	NOT SPECIFIED					
RABEPRAZOLE	Concomitant	NOT SPECIFIED					
RABEPRAZOLE	Concomitant	NOT SPECIFIED					
TETRACYCLINE	Concomitant	Capsules					
TRIMETHOPRIM-SULFAMETHOXAZOLE	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Urticaria	v.24.1	5 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000955955	0	2021-06-24	2021-06-24	Community		Spontaneous	Physician

Serious report?	Death:		Disability:		Congenital Anomaly:	
Not Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
59 Years	Female	66 Inch	195 Pound	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID VACCINE	Suspect	SOLUTION INTRAMUSCULAR			Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Exfoliative rash	v.24.1	
Rash	v.24.1	56 Days
Rash pruritic	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000956153	0	2021-06-25	2021-06-25	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
64 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AMLODIPINE	Concomitant	Tablets	Unknown				
ASPIRIN	Concomitant	NOT SPECIFIED					
ATORVASTATIN	Concomitant	Tablets					
COPAXONE	Concomitant						
FLOVENT	Concomitant	NOT SPECIFIED					
HYDERM	Concomitant	Cream					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml			Immunisation
VENTOLIN	Concomitant	NOT SPECIFIED	Inhalation				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.24.1	
Dyspnoea	v.24.1	
Palpitations	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000956156	0	2021-06-25	2021-06-25	Community		Spontaneous	Physician

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
45 Years	Female	168 Centimeter	117 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular		Once		COVID-19 immunisation
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		COVID-19 immunisation
TOPAMAX 100MG	Concomitant	Tablets					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthma	v.24.1	
Chest discomfort	v.24.1	
Pruritus	v.24.1	
Rash	v.24.1	
Skin burning sensation	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000956158	0	2021-06-25	2021-06-25	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
38 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Intermenstrual bleeding	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:07:47 AM
Initial Received Date:	2021-06-16 to 2021-07-30
Latest Received Date:	N/A
Total Number of Reports:	802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000956162	0	2021-06-25	2021-06-25	Community		Spontaneous	Other health professional

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
45 Years	Male		68 Kilogram	Recovering/resolving

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ADVAIR	Concomitant	NOT SPECIFIED					
DERMOVATE OINTMENT	Concomitant	OINTMENT TOPICAL					
FUCIDIN	Concomitant	NOT SPECIFIED					
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular		Once		COVID-19 immunisation
PERCOCET	Concomitant	Tablets	Unknown				
PREDNISONE	Concomitant	NOT SPECIFIED					
VENTOLIN NEBULE(S)	Concomitant	SOLUTION INHALATION					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bell's palsy	v.24.1	
Headache	v.24.1	
Malaise	v.24.1	
Ocular discomfort	v.24.1	
Paraesthesia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000956164	0	2021-06-25	2021-06-25	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
40 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml			COVID-19

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	24 Days
Disturbance in attention	v.24.1	
Fatigue	v.24.1	
Headache	v.24.1	
Impaired driving ability	v.24.1	
Impaired work ability	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Myalgia	v.24.1	
Physical disability	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000956165	0	2021-06-27	2021-06-27	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
40 Years	Female	163 Centimeter	79 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Menstruation delayed	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000956170	0	2021-06-25	2021-06-25	MAH		Spontaneous	Consumer/other non health professional

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
75 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		COVID-19 immunisation
RUPATADINE	Suspect		Unknown				Hypersensitivity
ZOPICLONE	Concomitant	Tablets					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Choking	v.24.1	
Erythema	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000956172	0	2021-06-27	2021-06-27	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
39 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Paraesthesia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000956173	0	2021-06-26	2021-06-26	Hospital		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
55 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID VACCINE	Suspect	SOLUTION INTRAMUSCULAR			Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Injection site erythema	v.24.1	
Injection site pain	v.24.1	
Injection site swelling	v.24.1	
Product administered at inappropriate site	v.24.1	
Product administration error	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000956178	0	2021-06-26	2021-06-26	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
36 Years	Female	122 Centimeter		Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal discomfort	v.24.1	
Breast pain	v.24.1	
Breast swelling	v.24.1	
Dyspnoea	v.24.1	
Pruritus	v.24.1	
Rash	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000956180	0	2021-06-27	2021-06-27	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
16 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_04406175

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR		0.3 ml	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pneumothorax	v.24.1	
Surgery	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000956182	0	2021-06-26	2021-06-26	Community		Spontaneous	Nurse

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
51 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Bursitis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000956184	0	2021-06-26	2021-06-26	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
25 Years	Female	63 Inch	150 Pound	Recovering/resolving

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR			Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Allodynia	v.24.1	18 Days
Herpes zoster	v.24.1	
Pain	v.24.1	
Rash	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000956188	0	2021-06-27	2021-06-27	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
41 Years	Female	60 Inch		Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	30.0 Microgram			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cystitis interstitial	v.24.1	
Dysuria	v.24.1	
Pollakiuria	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000956391	0	2021-06-28	2021-06-28	Hospital		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
74 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BISOPROLOL	Concomitant	Tablets					
EZETROL	Concomitant	Tablets					
GLICLAZIDE	Concomitant	Tablets					
HYDRALAZINE	Concomitant	Tablets					
LINAGLIPTIN	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	180.0 Microgram			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Deep vein thrombosis	v.24.1	19 Days
Lymphadenopathy	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Mediastinal mass	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000956394	0	2021-06-28	2021-06-28	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
27 Years	Female	167 Centimeter	50 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml			Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Loss of consciousness	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000956398	0	2021-06-28	2021-06-28	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
28 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
FLUOXETINE	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dehydration	v.24.1	5 Days
Intermenstrual bleeding	v.24.1	5 Days
Menstrual disorder	v.24.1	5 Days
Menstruation irregular	v.24.1	5 Days
Oligomenorrhoea	v.24.1	5 Days

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Thirst	v.24.1	5 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000956401	0	2021-06-28	2021-06-28	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
57 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID VACCINE	Suspect	SOLUTION INTRAMUSCULAR			Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Contusion	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000956402	0	2021-06-28	2021-06-28	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
64 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ARTHROTEC	Concomitant	Tablets					
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular				COVID-19 immunisation
TYLENOL	Concomitant	Tablets					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain upper	v.24.1	
Herpes zoster	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000956406	0	2021-06-28	2021-06-28	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
47 Years	Female	157 Centimeter	57 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular				
VITAMIN D	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.24.1	1 Days
Head discomfort	v.24.1	
Injection site pain	v.24.1	
Pain	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000956408	1	2021-06-28	2021-07-07	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
31 Years	Female	69 Inch	175 Pound	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CONTRACEPTIVES	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR		3.0 ml	Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Amenorrhoea	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000956413	0	2021-06-28	2021-06-28	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
43 Years	Male	178 Centimeter	93 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CBD OIL	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	1.0 Dosage forms			COVID-19 immunisation
VITAMIN B COMPLEX	Concomitant	NOT SPECIFIED					
VITAMIN D	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Drooling	v.24.1	
Dysphonia	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	
Feeling abnormal	v.24.1	
Gait disturbance	v.24.1	
Grip strength decreased	v.24.1	
Heart rate increased	v.24.1	
Hyperhidrosis	v.24.1	
Hypoaesthesia	v.24.1	
Joint range of motion decreased	v.24.1	
Limb discomfort	v.24.1	
Loss of personal independence in daily activities	v.24.1	
Mobility decreased	v.24.1	
Musculoskeletal stiffness	v.24.1	
Panic attack	v.24.1	
Paraesthesia	v.24.1	
Poor quality sleep	v.24.1	
Sensory loss	v.24.1	
Temperature perception test abnormal	v.24.1	
Tremor	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:07:47 AM
Initial Received Date:	2021-06-16 to 2021-07-30
Latest Received Date:	N/A
Total Number of Reports:	802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000956611	1	2021-06-29	2021-07-20	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	Yes	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
32 Years	Male			Fatal

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Circulatory collapse	v.24.1	
Drowning	v.24.1	
Myocardial infarction	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000956614	0	2021-06-29	2021-06-29	Community		Spontaneous	Other health professional

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
50 Years	Female	163 Centimeter	104 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID VACCINE	Suspect	SOLUTION INTRAMUSCULAR					COVID-19 immunisation
EFFEXOR	Concomitant	CAPSULE, EXTENDED RELEASE					
SULFAMETHOXAZOLE AND TRIMETHOPRIM	Concomitant	NOT SPECIFIED	Unknown				
VENTOLIN	Concomitant	NOT SPECIFIED	Inhalation				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Breast pain	v.24.1	
Breast swelling	v.24.1	
Influenza like illness	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Injection site pain	v.24.1	
Injection site swelling	v.24.1	
Pain in extremity	v.24.1	
Peripheral swelling	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000956615	0	2021-06-29	2021-06-29	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
56 Years	Male	185 Centimeter	111 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bell's palsy	v.24.1	
Hypoaesthesia	v.24.1	
Sensory disturbance	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000956618	0	2021-06-29	2021-06-29	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
53 Years	Female	165 Centimeter	63 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	0.5 ml			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypoaesthesia	v.24.1	
Injection site hypoaesthesia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000956619	0	2021-06-29	2021-06-29	Community		Spontaneous	Physician

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:	Yes	Hospitalization:	Yes	Other Medically Important Conditions:	

Patient Information

Age	Gender	Height	Weight	Report Outcome
79 Years				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Subcutaneous		Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dyspnoea	v.24.1	
Pulmonary embolism	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000956621	0	2021-06-29	2021-06-29	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
68 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular				COVID-19 immunisation
PANTOPRAZOLE	Concomitant	POWDER FOR SOLUTION INTRAVENOUS					
SYNTHROID	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Dizziness	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	
Gait inability	v.24.1	
Movement disorder	v.24.1	
Somnolence	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000956628	0	2021-06-29	2021-06-29	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
79 Years	Male	176 Centimeter	120 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
APIXABAN	Concomitant						
BISOPROLOL	Concomitant	Tablets					
CRESTOR	Concomitant	Tablets					
DILAUDID	Concomitant	NOT SPECIFIED					
DILTIAZEM	Concomitant	NOT SPECIFIED					
FLOMAX CR	Concomitant	TABLET (EXTENDED-RELEASE)					
INSPIOLTO RESPIMAT FOR ORAL INHALATION. WITH INSPIOLTO RESPIMAT INHALER	Concomitant	SOLUTION INHALATION					
LASIX	Concomitant	NOT SPECIFIED					
LYRICA	Concomitant	Capsules					

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MODAFINIL	Concomitant	NOT SPECIFIED					
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular		Once		COVID-19 immunisation
NABILONE	Concomitant	NOT SPECIFIED					
OXYBUTYNIN	Concomitant	NOT SPECIFIED	Unknown				
PANTOLOC	Concomitant	TABLET (ENTERIC-COATED)					
PROSCAR	Concomitant	Tablets					
PROZAC	Concomitant	NOT SPECIFIED					
VENTOLIN	Concomitant	NOT SPECIFIED	Inhalation				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Peripheral swelling	v.24.1	
Pruritus	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000956629	0	2021-06-29	2021-06-29	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female	163 Centimeter	66 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CALCIUM	Concomitant	NOT SPECIFIED					
CARBAMAZEPINE	Concomitant	NOT SPECIFIED					
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	0.5 ml			COVID-19 immunisation
EFFEXOR	Concomitant	CAPSULE, EXTENDED RELEASE					
EPIVAL	Concomitant	TABLET (ENTERIC-COATED)					
LOXAPINE	Concomitant	NOT SPECIFIED					
METAMUCIL	Concomitant	NOT SPECIFIED					

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
RESTORALAX	Concomitant	POWDER FOR SOLUTION ORAL					
SYNTHROID	Concomitant	NOT SPECIFIED					
VITAMIN D	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pruritus	v.24.1	
Rash	v.24.1	4 Days
Rash erythematous	v.24.1	
Skin warm	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000956631	0	2021-06-29	2021-06-29	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
101 Years	Female	145 Centimeter	55 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BISOPROLOL	Concomitant	Tablets					
HYDROCHLOROTHIAZIDE	Concomitant	Tablets					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Rash	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000956634	0	2021-06-29	2021-06-29	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
39 Years	Male	68 Inch	208 Pound	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
NOVORAPID	Concomitant	SOLUTION SUBCUTANEOUS					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR					COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Herpes zoster	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000956637	0	2021-06-29	2021-06-29	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
58 Years	Male	180 Centimeter	234 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		COVID-19

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Mobility decreased	v.24.1	
Oxygen saturation decreased	v.24.1	
Pneumonia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000956643	0	2021-06-29	2021-06-29	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID VACCINE	Suspect	SOLUTION INTRAMUSCULAR					
ASTRAZENECA COVID VACCINE	Suspect	SOLUTION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Irritable bowel syndrome	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000956783	0	2021-06-30	2021-06-30	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID VACCINE	Concomitant	SOLUTION INTRAMUSCULAR					
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Vaccination complication	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000956790	0	2021-06-30	2021-06-30	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cardiomyopathy	v.24.1	
Chest pain	v.24.1	
Fatigue	v.24.1	
Vaccine associated enhanced disease	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000956796	0	2021-06-30	2021-06-30	Hospital		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
47 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anxiety	v.24.1	
Aphasia	v.24.1	
Dyspnoea	v.24.1	
Mobility decreased	v.24.1	
Oropharyngeal discomfort	v.24.1	
Paraesthesia	v.24.1	
Swollen tongue	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000956800	0	2021-06-30	2021-06-30	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anxiety	v.24.1	
Asthenia	v.24.1	
Pain in extremity	v.24.1	
Paraesthesia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000956805	0	2021-06-30	2021-06-30	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
43 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ABILIFY	Concomitant	Tablets					
CLONAZEPAM	Concomitant	Tablets					
COVERSYL	Concomitant	Tablets					
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	100.0 Microgram			COVID-19 immunisation
PROZAC	Concomitant	Capsules					
TOPAMAX	Concomitant	Tablets					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.24.1	
Deep vein thrombosis	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dyspnoea	v.24.1	
Peripheral swelling	v.24.1	
Pulmonary embolism	v.24.1	
Thrombophlebitis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000956811	0	2021-07-01	2021-07-01	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
36 Years	Female	165 Centimeter	70 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect				Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Polymenorrhoea	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000956812	0	2021-06-30	2021-06-30	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
72 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID VACCINE	Suspect	SOLUTION INTRAMUSCULAR			Once	80.0 Days	COVID-19

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Alopecia	v.24.1	
Asthenia	v.24.1	
Balance disorder	v.24.1	
Dysmenorrhoea	v.24.1	
Fall	v.24.1	
Fatigue	v.24.1	
Feeling abnormal	v.24.1	
Gastrointestinal pain	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypersensitivity	v.24.1	
Nausea	v.24.1	
Tremor	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000956813	0	2021-07-01	2021-07-01	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
53 Years	Female	170 Centimeter	74 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular		Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Menstrual disorder	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000956816	0	2021-06-30	2021-06-30	Community		Spontaneous	Physician

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
63 Years	Male	170 Centimeter	86 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ALLOPURINOL	Concomitant	Tablets					
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular		Once		COVID-19 immunisation
NSAIDS	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bell's palsy	v.24.1	30 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000956818	0	2021-06-30	2021-06-30	Hospital		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
39 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID VACCINE	Suspect	SOLUTION INTRAMUSCULAR		0.5 ml	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Back pain	v.24.1	
Bell's palsy	v.24.1	
Subacute inflammatory demyelinating polyneuropathy	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000956819	0	2021-06-30	2021-06-30	Community		Spontaneous	Other health professional

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
36 Years	Female			Recovering/resolving

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BETADERM	Concomitant	NOT SPECIFIED					
HYCODAN	Concomitant	NOT SPECIFIED					
KETOCONAZOLE	Concomitant	Cream					
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	0.5 ml	Once		COVID-19 immunisation
ZOLOFT CAP 100MG	Concomitant	Capsules					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pruritus	v.24.1	
Urticaria	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000956824	0	2021-06-30	2021-06-30	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
52 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	0.5 ml	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.24.1	
Dyspnoea	v.24.1	
Fatigue	v.24.1	
Nausea	v.24.1	
Pericarditis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000956825	0	2021-06-30	2021-06-30	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
56 Years	Female	65 Inch	123 Pound	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR			Once		COVID-19 immunisation
SERTRALINE	Concomitant	Capsules					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Back pain	v.24.1	
Breast tenderness	v.24.1	
Dysmenorrhoea	v.24.1	
Postmenopausal haemorrhage	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000956828	0	2021-06-30	2021-06-30	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
38 Years	Female	61 Inch	115 Pound	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	0.5 ml	Once		COVID-19 immunisation
PRENATAL MULTIPLE VITAMIN	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Vaccination site rash	v.24.1	1 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000956829	0	2021-06-30	2021-06-30	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
48 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	0.5 ml	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Erythema	v.24.1	
Pruritus	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000956832	0	2021-06-30	2021-06-30	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
75 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID VACCINE	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular		Once		
ASTRAZENECA COVID VACCINE	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular		Once		
DILTIAZEM CD	Concomitant	CAPSULE, CONTROLLED-DELIVERY					
LORAZEPAM	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.24.1	
Fatigue	v.24.1	
Sensory loss	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Swelling	v.24.1	
Tremor	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
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Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000956835	0	2021-07-01	2021-07-01	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
72 Years	Male	174 Centimeter	90 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ALTACE	Concomitant	Capsules					
METFORMIN	Concomitant	Tablets					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml			Immunisation
ROSUVASTATIN	Concomitant	NOT SPECIFIED	Subcutaneous				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hemiparaesthesia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000956841	0	2021-07-01	2021-07-01	Hospital		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
69 Years	Female	60 Inch	160 Pound	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular				COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Deep vein thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000956846	0	2021-06-30	2021-06-30	Community		Spontaneous	Physician

Serious report?	Death:		Disability:		Congenital Anomaly:	
Not Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
24 Years				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect				Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pityriasis rosea	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000956996	0	2021-07-02	2021-07-02	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
43 Years	Female	163 Centimeter	58 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID VACCINE	Suspect	SOLUTION INTRAMUSCULAR		1.0 Dosage forms			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Asthenia	v.24.1	
Bruxism	v.24.1	
Conversion disorder	v.24.1	
Dehydration	v.24.1	
Diarrhoea	v.24.1	
Dyspnoea	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dysuria	v.24.1	
Exercise tolerance decreased	v.24.1	
Feeling abnormal	v.24.1	
Gait disturbance	v.24.1	
Gastrointestinal hypomotility	v.24.1	
Heart rate increased	v.24.1	
Hyperhidrosis	v.24.1	
Hypertension	v.24.1	
Mental impairment	v.24.1	
Muscle contractions involuntary	v.24.1	
Muscle spasms	v.24.1	
Muscle twitching	v.24.1	
Myalgia	v.24.1	
Pyrexia	v.24.1	
Thinking abnormal	v.24.1	
Tremor	v.24.1	
Urinary retention	v.24.1	
Weight decreased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000956997	0	2021-07-03	2021-07-03	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
14 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dysmenorrhoea	v.24.1	
Heavy menstrual bleeding	v.24.1	
Menstruation irregular	v.24.1	14 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000956998	1	2021-07-04	2021-07-04	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:		Disability:		Congenital Anomaly:	
Not Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	

Patient Information

Age	Gender	Height	Weight	Report Outcome
45 Years	Female			Recovered/resolved with sequelae

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Vision blurred	v.24.1	2 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000956999	0	2021-07-04	2021-07-04	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
54 Years			83 Kilogram	Recovering/resolving

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	0.5 ml	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain	v.24.1	
Feeling hot	v.24.1	
Heavy menstrual bleeding	v.24.1	
Menstruation irregular	v.24.1	

Canada Vigilance
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Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000957001	0	2021-07-03	2021-07-03	Community		Spontaneous	Nurse

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
36 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Injection site erythema	v.24.1	
Injection site induration	v.24.1	

Canada Vigilance
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Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000957003	0	2021-07-04	2021-07-04	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:		Disability:		Congenital Anomaly:	
Not Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	

Patient Information

Age	Gender	Height	Weight	Report Outcome
54 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypoaesthesia	v.24.1	

Canada Vigilance
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Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000957004	0	2021-07-04	2021-07-04	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
66 Years	Male		74 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular				COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.24.1	
Herpes zoster	v.24.1	
Malaise	v.24.1	

Canada Vigilance
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Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000957014	0	2021-07-03	2021-07-03	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
32 Years	Male	66 Inch	130 Pound	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COCAINE	Concomitant	NOT SPECIFIED					
CRACK COCAINE	Concomitant						
NARCAN	Concomitant		Intravenous (not otherwise specified)				
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	1.0 Dosage forms	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Loss of consciousness	v.24.1	1 Days

Canada Vigilance
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Initial Received Date: 2021-06-16 to 2021-07-30
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Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000957015	0	2021-07-02	2021-07-02	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
36 Years		67 Inch	220 Pound	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	0.5 ml	Once		Prophylaxis
VENLAFAXINE XR	Concomitant	CAPSULE, EXTENDED RELEASE					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dysmenorrhoea	v.24.1	
Hypomenorrhoea	v.24.1	
Polymenorrhoea	v.24.1	
Pyrexia	v.24.1	

Canada Vigilance
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Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000957018	0	2021-07-02	2021-07-02	Hospital		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
43 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular		Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.24.1	
Muscle spasms	v.24.1	
Skin burning sensation	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

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Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000957019	0	2021-07-03	2021-07-03	Hospital		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
48 Years	Female	173 Centimeter	83 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect						COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Myocarditis	v.24.1	
Troponin increased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

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Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000957020	1	2021-07-02	2021-07-11	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
40 Years	Female	62 Inch	129 Pound	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular		Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.24.1	
Fatigue	v.24.1	
Hypoaesthesia	v.24.1	
Impaired work ability	v.24.1	
Palpitations	v.24.1	
Paraesthesia	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Tremor	v.24.1	

Canada Vigilance
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Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000957023	0	2021-07-02	2021-07-02	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
69 Years	Female	180 Centimeter	109 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ELIQUIS FILM COATED	Concomitant	Tablets					
FERROUS FUMARATE	Concomitant	NOT SPECIFIED					
HYDREA CAP 500MG	Concomitant	Capsules					
LAMOTRIGINE	Concomitant	Tablets					
LASIX	Concomitant	NOT SPECIFIED					
METOPROLOL	Concomitant	Tablets					
MEZAVANT	Concomitant	TABLET (DELAYED AND EXTENDED RELEASE)					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				COVID-19 immunisation
SPIRONOLACTONE	Concomitant	Tablets					

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
SYNTHROID	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Breast oedema	v.24.1	
Breast swelling	v.24.1	

Canada Vigilance
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Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000957211	0	2021-07-05	2021-07-05	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
29 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Lip swelling	v.24.1	
Peripheral swelling	v.24.1	
Rash erythematous	v.24.1	
Rash papular	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

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Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000957212	0	2021-07-05	2021-07-05	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
36 Years	Female	178 Centimeter	68 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect				Once		COVID-19

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dysmenorrhoea	v.24.1	36 Days
Heavy menstrual bleeding	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

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Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000957214	0	2021-07-05	2021-07-05	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
52 Years	Female	165 Centimeter	69 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ATIVAN	Concomitant	NOT SPECIFIED					
CAMBIA	Concomitant	POWDER FOR SOLUTION ORAL					
CELEXA	Concomitant	Tablets					
ELETRIPTAN	Concomitant	NOT SPECIFIED					
MELATONIN	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR			Once		COVID-19 prophylaxis
TRANEXAMIC ACID	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypoaesthesia	v.24.1	
Hypoaesthesia oral	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Lip discolouration	v.24.1	
Paraesthesia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
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Report Information ***AER = Adverse Reaction Report*

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000957435	0	2021-07-06	2021-07-06	Hospital		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male	175 Centimeter	89 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ALLOPURINOL	Concomitant	Tablets					
ASPIRIN	Concomitant	NOT SPECIFIED					
DILTIAZEM	Concomitant	CAPSULE, SUSTAINED-RELEASE					
FENOFIBRATE	Concomitant	NOT SPECIFIED					
GLICLAZIDE	Concomitant	Tablets					
JANUMET	Concomitant	NOT SPECIFIED	Unknown				
METOPROLOL	Concomitant	Tablets	Unknown				
NITROGLYCERIN	Concomitant	TABLET (EXTENDED-RELEASE)					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	30.0 Microgram			COVID-19 immunisation

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ROSUVASTATIN	Concomitant	NOT SPECIFIED	Subcutaneous				
TELMISARTAN	Concomitant	Tablets					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Back pain	v.24.1	
Facial paralysis	v.24.1	
Guillain-Barre syndrome	v.24.1	
Muscular weakness	v.24.1	
Pain in extremity	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
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Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000957437	0	2021-07-06	2021-07-06	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
50 Years	Female	66 Inch	200 Pound	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blister	v.24.1	

Canada Vigilance
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Report Runtime:	2022-05-07 - 01:07:47 AM
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Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000957442	0	2021-07-06	2021-07-06	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
30 Years	Male	188 Centimeter	310 Pound	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cyanosis	v.24.1	3 Days
Myocardial infarction	v.24.1	
Pallor	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

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Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000957447	0	2021-07-06	2021-07-06	Community		Spontaneous	Pharmacist

Serious report?	Death:		Disability:		Congenital Anomaly:	
Not Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
45 Years	Female	64 Inch	215 Pound	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular		Once		COVID-19 immunisation
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular		Once		COVID-19 immunisation
WARFARIN	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
International normalised ratio increased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
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Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000957451	0	2021-07-06	2021-07-06	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
30 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR			Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.24.1	
Loss of consciousness	v.24.1	
Tremor	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000957455	0	2021-07-06	2021-07-06	Community		Spontaneous	Physician

Serious report?	Death:		Disability:		Congenital Anomaly:	
Not Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	

Patient Information

Age	Gender	Height	Weight	Report Outcome
49 Years	Male	66 Inch	215 Pound	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		COVID-19 immunisation
PROZAC CAP 20MG	Concomitant	Capsules					
TRAMADOL HYDROCHLORIDE	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000957456	0	2021-07-06	2021-07-06	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
73 Years	Female	67 Inch	128 Pound	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	0.5 ml			COVID-19 immunisation
FUCIDIN	Concomitant	NOT SPECIFIED					
PROLIA	Concomitant	SOLUTION SUBCUTANEOUS					
RATIO-TECNAL	Concomitant	Tablets					
ROSUVASTATIN	Concomitant	NOT SPECIFIED					
SALICYLATES NOS	Concomitant						
SYNTHROID	Concomitant	NOT SPECIFIED					
TELMISARTAN	Concomitant	Tablets					
ZOPICLONE	Concomitant	Tablets					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Injection site erythema	v.24.1	
Injection site pruritus	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000957461	0	2021-07-06	2021-07-06	Community		Spontaneous	Physician

Serious report?	Death:		Disability:		Congenital Anomaly:	
Not Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
52 Years	Female	162 Centimeter	139 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AVAMYS	Concomitant	SPRAY, METERED DOSE					
BETAMETHASONE	Concomitant	NOT SPECIFIED					
CLOTRIMAZOLE	Concomitant	NOT SPECIFIED					
MAXALT	Concomitant	Tablets					
MIRTAZAPINE	Concomitant	Tablets					
PERCOCET	Concomitant	Tablets					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR			Once	92.0 Days	
TRAZODONE	Concomitant	Tablets					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Rash	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000957463	0	2021-07-06	2021-07-06	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SUSPENSION INTRAMUSCULAR			Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pain in extremity	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000957466	0	2021-07-06	2021-07-06	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
74 Years	Female	160 Centimeter	70 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ARTHROTEC	Concomitant	Tablets					
BETNOVATE	Concomitant	NOT SPECIFIED					
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular				
DEPO-MEDROL	Concomitant	SUSPENSION INTRA-ARTICULAR					
VITAMIN D	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Erythema	v.24.1	
Rash	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Swelling	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000957467	0	2021-07-06	2021-07-06	Community		Spontaneous	Other health professional

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Disturbance in attention	v.24.1	
Dizziness	v.24.1	
Fatigue	v.24.1	
Myalgia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000957468	0	2021-07-06	2021-07-06	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID VACCINE	Suspect	SOLUTION INTRAMUSCULAR			Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Guillain-Barre syndrome	v.24.1	
Influenza like illness	v.24.1	
Tremor	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000957472	0	2021-07-06	2021-07-06	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Dizziness	v.24.1	
Dyspnoea	v.24.1	
Headache	v.24.1	
Heart rate irregular	v.24.1	
Hypoaesthesia	v.24.1	
Malaise	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Muscle tightness	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000957476	0	2021-07-06	2021-07-06	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
67 Years	Female	164 Centimeter	60 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ANUSOL	Concomitant	NOT SPECIFIED					
CALCIUM CITRATE	Concomitant	NOT SPECIFIED					
CIPRALEX	Concomitant	Tablets					
CLOBETASOL CREAM 0.05%	Concomitant	Cream					
CLOTRIMADERM VAG CREAM 2%	Concomitant	Cream					
DULCOLAX	Concomitant	Suppository					
FERROUS FUMARATE	Concomitant	NOT SPECIFIED					
FUCIDIN	Concomitant	NOT SPECIFIED					
HYDROMORPHONE	Concomitant	NOT SPECIFIED					
KETODERM CREAM 2%	Concomitant	Cream					
LORAZEPAM	Concomitant	NOT SPECIFIED					
NAPROXEN	Concomitant	NOT SPECIFIED					

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR					COVID-19 immunisation
QUETIAPINE	Concomitant	Tablets					
ROCALTROL	Concomitant	Capsules					
STIEVA-A	Concomitant	NOT SPECIFIED					
SYNTHROID	Concomitant	NOT SPECIFIED					
TEARS NATURALE	Concomitant	Ophthalmic					
VAGIFEM	Concomitant	Vaginal suppository					
VITAMIN D	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Dysgeusia	v.24.1	
Fatigue	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000957635	0	2021-07-07	2021-07-07	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
29 Years	Female	163 Centimeter	49 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR			Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Heavy menstrual bleeding	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000957642	0	2021-07-07	2021-07-07	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
66 Years	Male			Recovering/resolving

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.24.1	
Pericarditis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000957646	0	2021-07-07	2021-07-07	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
31 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR			Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.24.1	
Paraesthesia	v.24.1	
Pericarditis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000957649	0	2021-07-07	2021-07-07	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
30 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR			Once		COVID-19

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Limb discomfort	v.24.1	
Malaise	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000957902	0	2021-07-08	2021-07-08	Community		Spontaneous	Physician

Serious report?	Death:		Disability:		Congenital Anomaly:	
Not Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	

Patient Information

Age	Gender	Height	Weight	Report Outcome
33 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular		Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.24.1	
Hypotonic-hyporesponsive episode	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000957903	0	2021-07-08	2021-07-08	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
32 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	0.5 ml	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Vaccination site cellulitis	v.24.1	
Vaccination site erythema	v.24.1	
Vaccination site pain	v.24.1	
Vaccination site rash	v.24.1	
Vaccination site swelling	v.24.1	
Vaccination site warmth	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000957905	0	2021-07-08	2021-07-08	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
54 Years	Female	122 Centimeter		Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect						COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Discomfort	v.24.1	
Dysgeusia	v.24.1	3 Days
Dyspnoea	v.24.1	
Fatigue	v.24.1	
Headache	v.24.1	
Heart rate increased	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypertension	v.24.1	
Limb discomfort	v.24.1	
Mobility decreased	v.24.1	
Tongue disorder	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000957906	0	2021-07-08	2021-07-08	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
74 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				COVID-19 immunisation
VITAMIN D	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Pain	v.24.1	
Pyrexia	v.24.1	
Skin discolouration	v.24.1	
Skin hypopigmentation	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000957909	0	2021-07-08	2021-07-08	Hospital		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
26 Years	Male			Recovering/resolving

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Subcutaneous		Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pericarditis	v.24.1	1 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000957911	0	2021-07-08	2021-07-08	Hospital		Spontaneous	Pharmacist

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:	Yes	Other Medically Important Conditions:	

Patient Information

Age	Gender	Height	Weight	Report Outcome
72 Years	Male	175 Centimeter	76 Kilogram	Recovering/resolving

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETAMINOPHEN	Concomitant	Tablets					
ACETYLSALICYLIC ACID	Concomitant	NOT SPECIFIED	Unknown				
EVOLOCUMAB	Concomitant						
EZETIMIBE	Concomitant	Tablets					
HYDROCHLOROTHIAZIDE	Concomitant	Tablets					
HYDROMORPHONE	Concomitant	NOT SPECIFIED					
METOPROLOL	Concomitant	NOT SPECIFIED	Unknown				
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Once		COVID-19 immunisation
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Once		COVID-19 immunisation
VALSARTAN	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain	v.24.1	
Chest pain	v.24.1	
Dyspnoea	v.24.1	
Pain	v.24.1	
Pleuropericarditis	v.24.1	
Pyrexia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000957913	0	2021-07-08	2021-07-08	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
62 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bell's palsy	v.24.1	
Peripheral swelling	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000957916	0	2021-07-08	2021-07-08	Community		Spontaneous	Physician

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
55 Years	Female	172 Centimeter	72 Kilogram	Recovering/resolving

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Lung infiltration	v.24.1	
Lung opacity	v.24.1	
Myocarditis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000957919	0	2021-07-08	2021-07-08	Community		Spontaneous	Pharmacist

Serious report?	Death:		Disability:		Congenital Anomaly:	
Not Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
48 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	1.0 Dosage forms			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cough	v.24.1	
Dyspepsia	v.24.1	
Dyspnoea	v.24.1	
Fatigue	v.24.1	
Pain in extremity	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000958145	0	2021-07-09	2021-07-09	Hospital		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
72 Years	Male			Recovering/resolving

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASA	Concomitant	NOT SPECIFIED					
CELECOXIB	Concomitant	Capsules					
CRESTOR	Concomitant	Tablets					
GLUMETZA	Concomitant	TABLET (EXTENDED-RELEASE)					
PERINDOPRIL	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	30.0 Microgram			COVID-19 immunisation
QUETIAPINE	Concomitant	Tablets					
REPATHA	Concomitant	SOLUTION SUBCUTANEOUS					
SEMAGLUTIDE	Concomitant	SOLUTION SUBCUTANEOUS					
over the counter supplements	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pulmonary embolism	v.24.1	6 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000958148	0	2021-07-09	2021-07-09	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
28 Years	Female	165 Centimeter	68 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular		Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Chills	v.24.1	
Decreased appetite	v.24.1	
Headache	v.24.1	
Hyperhidrosis	v.24.1	
Injection site pain	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pain	v.24.1	
Pyrexia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000958149	0	2021-07-09	2021-07-09	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
47 Years	Female	65 Inch	145 Pound	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml			
SYNTHROID	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Electric shock sensation	v.24.1	
Nasopharyngitis	v.24.1	
Paraesthesia	v.24.1	
Pyrexia	v.24.1	
Skin burning sensation	v.24.1	
Sleep disorder	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000958150	0	2021-07-09	2021-07-09	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
56 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Acute lymphocytic leukaemia	v.24.1	
Fatigue	v.24.1	
Headache	v.24.1	
Pyrexia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000958152	0	2021-07-09	2021-07-09	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
43 Years	Female	177 Centimeter	65 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	1.0 Dosage forms	Once		COVID-19

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Intermenstrual bleeding	v.24.1	
Menstruation irregular	v.24.1	
Oligomenorrhoea	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000958153	0	2021-07-10	2021-07-10	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
59 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	0.5 ml	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cellulitis	v.24.1	
Injection site erythema	v.24.1	
Injection site pruritus	v.24.1	
Injection site warmth	v.24.1	
Lymph node pain	v.24.1	
Lymphadenopathy	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000958155	0	2021-07-10	2021-07-10	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
50 Years	Female	62 Inch	175 Pound	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	2.0 Dosage forms			COVID-19 prophylaxis
YAZ	Concomitant	Tablets					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Condition aggravated	v.24.1	
Heavy menstrual bleeding	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000958158	0	2021-07-09	2021-07-09	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
35 Years	Female	68 Inch	317 Pound	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	0.5 ml	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.24.1	
Erythema	v.24.1	
Headache	v.24.1	
Hyperhidrosis	v.24.1	
Injection site swelling	v.24.1	
Pain	v.24.1	
Peripheral swelling	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pyrexia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000958159	0	2021-07-09	2021-07-09	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
47 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
LOLO	Concomitant	Tablets					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR			Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.24.1	
Eye pain	v.24.1	
Head discomfort	v.24.1	
Injection site pain	v.24.1	42 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000958160	0	2021-07-11	2021-07-11	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
32 Years	Female	168 Centimeter	99 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.24.1	
Dizziness	v.24.1	
Flushing	v.24.1	
Hypoaesthesia	v.24.1	
Loss of consciousness	v.24.1	
Lymph node pain	v.24.1	
Muscular weakness	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Musculoskeletal stiffness	v.24.1	
Myalgia	v.24.1	
Nausea	v.24.1	
Neck pain	v.24.1	
Palpitations	v.24.1	
Paraesthesia	v.24.1	
Pruritus	v.24.1	
Rash	v.24.1	
Tinnitus	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000958163	0	2021-07-09	2021-07-09	Community		Spontaneous	Physician

Serious report?	Death:		Disability:		Congenital Anomaly:	
Not Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female	159 Centimeter	82 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
DYMISTA NASENSPRAY, SUSPENSION	Concomitant						
EPIPEN	Concomitant	SOLUTION INTRAMUSCULAR					
FERROUS FUMARATE	Concomitant	NOT SPECIFIED					
LABETALOL	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR					
PRENATAL MULTIPLE VITAMIN	Concomitant	NOT SPECIFIED					
TECTA	Concomitant	NOT SPECIFIED					
nipple cream	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Herpes zoster	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000958164	0	2021-07-09	2021-07-09	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:		Disability:		Congenital Anomaly:	
Not Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
14 Years	Female	162 Centimeter	141 Pound	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
OMBRELLE	Concomitant	LOTION					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Rash	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000958167	0	2021-07-10	2021-07-10	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
68 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Back pain	v.24.1	
Hypotension	v.24.1	
Syncope	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000958168	0	2021-07-09	2021-07-09	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
69 Years	Female	61 Inch	81 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular		Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pelvic venous thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000958170	0	2021-07-09	2021-07-09	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:		Disability:		Congenital Anomaly:	
Not Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID VACCINE	Suspect	SOLUTION INTRAMUSCULAR					
ASTRAZENECA COVID VACCINE	Suspect	SOLUTION INTRAMUSCULAR				90.0 Days	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pruritus	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000958171	0	2021-07-09	2021-07-09	Community		Spontaneous	Physician

Serious report?	Death:		Disability:		Congenital Anomaly:	
Not Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
27 Years				Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
KYLEENA	Concomitant	INSERT (EXTENDED-RELEASE)					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		
SERTRALINE	Concomitant	Capsules					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Herpes zoster	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000958172	0	2021-07-09	2021-07-09	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
50 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BRICANYL TURBUHALER	Concomitant	POWDER, METERED DOSE					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	1.0 Dosage forms	Once		Immunisation
SYMBICORT 200/6	Concomitant	NOT SPECIFIED	Unknown				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cellulitis	v.24.1	
Chills	v.24.1	
Fatigue	v.24.1	
Headache	v.24.1	
Nausea	v.24.1	
Pyrexia	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Vaccination site erythema	v.24.1	
Vaccination site induration	v.24.1	
Vaccination site pain	v.24.1	
Vaccination site warmth	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000958175	0	2021-07-09	2021-07-09	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR			Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Axillary pain	v.24.1	
Chest pain	v.24.1	
Discomfort	v.24.1	
Pain	v.24.1	
Painful respiration	v.24.1	
Swelling	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000958182	0	2021-07-12	2021-07-12	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
27 Years				Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anal incontinence	v.24.1	
Autoimmune disorder	v.24.1	
Back pain	v.24.1	
Chest pain	v.24.1	
Decreased appetite	v.24.1	
Dizziness	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Electric shock sensation	v.24.1	
Fibrin D dimer increased	v.24.1	
Headache	v.24.1	
Insomnia	v.24.1	
Loss of personal independence in daily activities	v.24.1	
Neck pain	v.24.1	
Paraesthesia	v.24.1	
Sensory loss	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000958378	0	2021-07-12	2021-07-12	Community		Spontaneous	Physician

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
70 Years	Female	153 Centimeter	63 Kilogram	Recovering/resolving

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
NAPROXEN	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthritis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000958380	0	2021-07-12	2021-07-12	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR			Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.24.1	
Computerised tomogram abnormal	v.24.1	
Diplopia	v.24.1	
Dyspnoea	v.24.1	
Head discomfort	v.24.1	
Malaise	v.24.1	
Paraesthesia	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Photophobia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000958381	0	2021-07-12	2021-07-12	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bedridden	v.24.1	
Dysmenorrhoea	v.24.1	
Menstrual disorder	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000958611	0	2021-07-13	2021-07-13	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
54 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular		Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Chest discomfort	v.24.1	
Chest pain	v.24.1	
Chills	v.24.1	
Fatigue	v.24.1	
Lethargy	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Malaise	v.24.1	
Pain	v.24.1	
Pyrexia	v.24.1	
Swollen tongue	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:07:47 AM
Initial Received Date:	2021-06-16 to 2021-07-30
Latest Received Date:	N/A
Total Number of Reports:	802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000958612	0	2021-07-13	2021-07-13	Community		Spontaneous	Nurse

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
48 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dyspnoea exertional	v.24.1	
Wheezing	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000958613	0	2021-07-13	2021-07-13	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
20 Years	Female	66 Inch	159 Pound	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenopia	v.24.1	
Eyelid ptosis	v.24.1	7 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000958616	0	2021-07-13	2021-07-13	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
75 Years	Female	173 Centimeter	69 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	0.5 ml	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Diarrhoea	v.24.1	22 Days
Dizziness postural	v.24.1	45 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:07:47 AM
Initial Received Date:	2021-06-16 to 2021-07-30
Latest Received Date:	N/A
Total Number of Reports:	802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000958617	0	2021-07-13	2021-07-13	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
62 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pain in extremity	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000958619	0	2021-07-13	2021-07-13	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:		Disability:	Yes	Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
40 Years	Female	170 Centimeter	160 Pound	Recovering/resolving

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
HYALURONATE SODIUM	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				COVID-19 immunisation
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				COVID-19 immunisation
PREGABALIN	Concomitant	Capsules					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.24.1	
Injection site pain	v.24.1	
Myalgia	v.24.1	
Pain in extremity	v.24.1	
Physical disability	v.24.1	
Swelling	v.24.1	
Synovitis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000958846	0	2021-07-14	2021-07-14	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
57 Years	Male	178 Centimeter	71 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blindness	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000958848	0	2021-07-14	2021-07-14	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
58 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		COVID-19 immunisation
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR					COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Herpes zoster	v.24.1	
Pain	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pruritus	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000958849	0	2021-07-14	2021-07-14	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
40 Years				Recovering/resolving

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Subcutaneous				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Herpes zoster	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000958850	0	2021-07-14	2021-07-14	Hospital		Spontaneous	Physician

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
62 Years	Male		205 Pound	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR			Once	68.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pulmonary embolism	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000958852	0	2021-07-14	2021-07-14	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
61 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blister	v.24.1	
Erythema	v.24.1	
Rash	v.24.1	
Varicella	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000958853	0	2021-07-14	2021-07-14	Hospital		Spontaneous	Pharmacist

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:	Yes	Other Medically Important Conditions:	

Patient Information

Age	Gender	Height	Weight	Report Outcome
25 Years	Male	177 Centimeter	82 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect			0.5 ml	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.24.1	
Disease progression	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000958858	0	2021-07-14	2021-07-14	MAH		Study	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
59 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID VACCINE	Suspect		Unknown				COVID-19 immunisation
LIRAGLUTIDE	Suspect		Subcutaneous				Weight control
LIRAGLUTIDE	Suspect		Subcutaneous	2.4 Milligram	1 every 1 Days		Weight control
LIRAGLUTIDE	Suspect		Subcutaneous	0.6 Milligram	1 every 1 Days		Weight control
LIRAGLUTIDE	Suspect		Subcutaneous				Weight control

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Diarrhoea	v.24.1	
Nausea	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000959041	0	2021-07-15	2021-07-15	Hospital		Spontaneous	Physician

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
55 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASPIRIN	Concomitant	NOT SPECIFIED					
METOPROLOL	Concomitant	Tablets					
PANTOPRAZOLE	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				COVID-19 immunisation
TOPIRAMATE	Concomitant	NOT SPECIFIED					
ULTIBRO BREEZHALER	Concomitant						
VENTOLIN	Concomitant	NOT SPECIFIED	Inhalation				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Lymphadenopathy	v.24.1	
Neuropathy peripheral	v.24.1	
Rash	v.24.1	
Type III immune complex mediated reaction	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000959047	0	2021-07-15	2021-07-15	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaemia	v.24.1	
Blast cells present	v.24.1	
Contusion	v.24.1	
Haematological malignancy	v.24.1	
Leukocytosis	v.24.1	
Thrombocytopenia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000959050	0	2021-07-15	2021-07-15	Hospital		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
20 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect						COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.24.1	
Myocarditis	v.24.1	
Pericarditis	v.24.1	
Pleuritic pain	v.24.1	
Sinus tachycardia	v.24.1	
Troponin increased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000959067	0	2021-07-15	2021-07-15	Hospital		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
28 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Subcutaneous				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypersensitivity	v.24.1	
Oedema	v.24.1	
Pharyngeal swelling	v.24.1	
Rash	v.24.1	
Throat tightness	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000959070	0	2021-07-15	2021-07-15	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
38 Years	Female	213 Centimeter		Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect						COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Skin reaction	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000959071	0	2021-07-15	2021-07-15	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
33 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood pressure diastolic decreased	v.24.1	
Blood pressure systolic increased	v.24.1	
Chest discomfort	v.24.1	
Chest pain	v.24.1	
Fatigue	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000959072	0	2021-07-16	2021-07-16	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
42 Years	Female	163 Centimeter	77 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	1.0 Dosage forms	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.24.1	
Heart rate increased	v.24.1	
Hot flush	v.24.1	
Menstruation irregular	v.24.1	
Palpitations	v.24.1	
Respiratory rate decreased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000959076	0	2021-07-15	2021-07-15	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
27 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Heavy menstrual bleeding	v.24.1	12 Days
Polymenorrhoea	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000959077	0	2021-07-15	2021-07-15	Hospital		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
71 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR		0.3 ml		84.0 Days	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest discomfort	v.24.1	
Myocarditis	v.24.1	
Palpitations	v.24.1	
Pericarditis	v.24.1	
Tachycardia	v.24.1	
Troponin increased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000959079	0	2021-07-15	2021-07-15	Hospital		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
72 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR			Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Aphasia	v.24.1	
Asthenia	v.24.1	
Cerebrovascular accident	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000959081	0	2021-07-15	2021-07-15	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
62 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR			Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anxiety	v.24.1	
Cough	v.24.1	
Disease recurrence	v.24.1	
Dysphagia	v.24.1	
Fear	v.24.1	
Hypersensitivity	v.24.1	
Lymphadenopathy	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Sensation of foreign body	v.24.1	
Throat clearing	v.24.1	
Tooth impacted	v.24.1	
Upper-airway cough syndrome	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000959082	0	2021-07-15	2021-07-15	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
66 Years	Female	63 Inch	215 Pound	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ABILIFY	Concomitant	Tablets					
EFFEXOR	Concomitant	CAPSULE, EXTENDED RELEASE					
ELTROXIN	Concomitant	Tablets					
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Lymphadenopathy	v.24.1	
Pain	v.24.1	
Peripheral swelling	v.24.1	
Pharyngeal swelling	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pruritus	v.24.1	
Rash	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000959260	0	2021-07-16	2021-07-16	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
53 Years	Female	64 Inch	134 Pound	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AVAMYS	Concomitant	SPRAY, METERED DOSE					
CLINDOXYL GEL	Concomitant	GEL					
NAPROSYN	Concomitant	Tablets					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR			Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Diarrhoea	v.24.1	
Fluid replacement	v.24.1	
Headache	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000959268	0	2021-07-16	2021-07-16	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
42 Years	Female	173 Centimeter	72 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
DEHYDROEPIANDROSTERONE	Concomitant	NOT SPECIFIED					
DESICCATED THYROID (PORCINE)	Concomitant	NOT SPECIFIED					
FERAMAX	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Menstruation delayed	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000959283	0	2021-07-16	2021-07-16	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
12 Years	Male	64 Inch	108 Pound	Recovered/resolved with sequelae

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR			Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	
Pollakiuria	v.24.1	
Thirst	v.24.1	
Type 1 diabetes mellitus	v.24.1	
Weight decreased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000959284	0	2021-07-16	2021-07-16	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
46 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	0.5 Milligram	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dysphonia	v.24.1	
Dyspnoea	v.24.1	
Reaction to excipient	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000959285	0	2021-07-16	2021-07-16	Hospital		Spontaneous	Physician

Serious report?	Death:	Yes	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
97 Years	Female		57 Kilogram	Fatal

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
LOVENOX	Concomitant	SOLUTION SUBCUTANEOUS					
NORVASC	Concomitant	Tablets					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml			
SERTRALINE	Concomitant	Capsules					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Altered state of consciousness	v.24.1	
Confusional state	v.24.1	
Labile hypertension	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000959473	0	2021-07-19	2021-07-19	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
14 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CETIRIZINE	Concomitant	Tablets					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypersensitivity	v.24.1	
Lip swelling	v.24.1	
Pruritus	v.24.1	
Swelling face	v.24.1	
Urticaria	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000959474	0	2021-07-19	2021-07-19	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
60 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect						
REACTINE	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Swelling face	v.24.1	1 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000959476	0	2021-07-19	2021-07-19	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
21 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anxiety	v.24.1	
Hypoaesthesia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000959477	0	2021-07-19	2021-07-19	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:		Disability:		Congenital Anomaly:	
Not Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
37 Years	Female	64 Inch	124 Pound	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Heavy menstrual bleeding	v.24.1	
Menstrual disorder	v.24.1	
Menstruation delayed	v.24.1	
Oligomenorrhoea	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000959478	0	2021-07-19	2021-07-19	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
36 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CYCLOBENZAPRINE	Concomitant	NOT SPECIFIED					
NAPROXEN	Concomitant	NOT SPECIFIED					
PANTOLOC	Concomitant	TABLET (ENTERIC-COATED)					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR			Once	44.0 Days	
REACTINE	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Urticaria	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000959479	0	2021-07-19	2021-07-19	Community		Spontaneous	Other health professional

Serious report?	Death:	Yes	Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
90 Years	Female	165 Centimeter	62 Pound	Fatal

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AMLODIPINE	Concomitant	Tablets	Unknown				
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	0.5 ml			COVID-19 immunisation
DIVALPROEX SODIUM	Concomitant	NOT SPECIFIED					
EFFEXOR-XR	Concomitant	CAPSULE, EXTENDED RELEASE					
ELTROXIN	Concomitant	Tablets					
TRAZODONE	Concomitant	Tablets					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Circulatory collapse	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hyperhidrosis	v.24.1	
Skin discolouration	v.24.1	
Unresponsive to stimuli	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000959481	0	2021-07-19	2021-07-19	Community		Spontaneous	Nurse

Serious report?	Death:		Disability:		Congenital Anomaly:	
Not Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	

Patient Information

Age	Gender	Height	Weight	Report Outcome
54 Years	Female	164 Centimeter	94 Kilogram	Recovering/resolving

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Urticaria	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000959482	1	2021-07-19	2021-08-04	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
59 Years	Female			Recovered/resolved with sequelae

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood pressure fluctuation	v.24.1	
Lip pruritus	v.24.1	
Malaise	v.24.1	
Tachycardia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000959483	0	2021-07-19	2021-07-19	MAH		Published	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
63 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Duplicate	E2B_04452507

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID VACCINE	Suspect	SOLUTION INTRAMUSCULAR					COVID-19 immunisation
HEPARIN SODIUM	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)				Anticoagulant therapy

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Thrombocytopenia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000959681	0	2021-07-20	2021-07-20	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
36 Years	Male	181 Centimeter	64 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Axillary pain	v.24.1	
Fatigue	v.24.1	
Lymphadenopathy	v.24.1	
Musculoskeletal discomfort	v.24.1	
Pain	v.24.1	
Pyrexia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:07:47 AM
Initial Received Date:	2021-06-16 to 2021-07-30
Latest Received Date:	N/A
Total Number of Reports:	802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000959682	0	2021-07-20	2021-07-20	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
50 Years	Male	69 Inch	200 Pound	Recovered/resolved with sequelae

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Myocarditis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000959684	0	2021-07-20	2021-07-20	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
17 Years	Female	165 Centimeter	54 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypoaesthesia	v.24.1	
Sensory loss	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000959685	0	2021-07-20	2021-07-20	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
36 Years	Male	74 Inch	152 Pound	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ADDERALL XR	Concomitant	CAPSULE, EXTENDED RELEASE					
MULTIVITAMINE(S)	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Once		COVID-19 immunisation
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pericarditis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000959687	0	2021-07-20	2021-07-20	Community		Spontaneous	Physician

Serious report?	Death: Yes	Disability:	Congenital Anomaly:
Serious	Life Threatening:	Hospitalization:	Other Medically Important Conditions:

Patient Information

Age	Gender	Height	Weight	Report Outcome
72 Years	Male		69 Kilogram	Fatal

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Sudden death	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000959689	0	2021-07-20	2021-07-20	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
77 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Balance disorder	v.24.1	
Fall	v.24.1	
Fibromyalgia	v.24.1	
Myalgia	v.24.1	
Pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:07:47 AM
Initial Received Date:	2021-06-16 to 2021-07-30
Latest Received Date:	N/A
Total Number of Reports:	802 Report(s)

Report Information

***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000959889	0	2021-07-21	2021-07-21	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
40 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	1.0 Dosage forms			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	
Headache	v.24.1	
Vision blurred	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000959894	1	2021-07-21	2021-08-06	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Appendicectomy	v.24.1	
Appendicitis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000959895	0	2021-07-21	2021-07-21	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
77 Years	Male	68 Inch	173 Pound	Recovering/resolving

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASA	Concomitant	NOT SPECIFIED	Unknown				
ATORVASTATIN	Concomitant	Tablets	Oral				
BISOPROLOL	Concomitant	Tablets	Unknown				
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	0.5 ml	Once		COVID-19 immunisation
SHINGRIX	Concomitant	SUSPENSION INTRAMUSCULAR					
VITAMIN C	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cellulitis	v.24.1	37 Days

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Erythema	v.24.1	37 Days
Herpes zoster	v.24.1	37 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:07:47 AM
Initial Received Date:	2021-06-16 to 2021-07-30
Latest Received Date:	N/A
Total Number of Reports:	802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000960067	0	2021-07-22	2021-07-22	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
44 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID VACCINE	Suspect		Intramuscular				COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Heavy menstrual bleeding	v.24.1	
Menstruation irregular	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000960069	0	2021-07-22	2021-07-22	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:		Disability:	Yes	Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
71 Years	Male	64 Inch	130 Pound	Recovering/resolving

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	0.5 ml	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Herpes zoster	v.24.1	
Loss of personal independence in daily activities	v.24.1	
Neuralgic amyotrophy	v.24.1	
Oedema	v.24.1	
Pain	v.24.1	
Paralysis	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Secretion discharge	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000960070	0	2021-07-22	2021-07-22	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
48 Years	Female	65 Inch	145 Pound	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Postmenopausal haemorrhage	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000960072	0	2021-07-22	2021-07-22	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:		Disability:	Yes	Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:	Yes	Other Medically Important Conditions:	

Patient Information

Age	Gender	Height	Weight	Report Outcome
43 Years	Female	174 Centimeter	70 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Back pain	v.24.1	
Hypoaesthesia	v.24.1	
Pain	v.24.1	
Pain in extremity	v.24.1	
Paraesthesia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:07:47 AM
Initial Received Date:	2021-06-16 to 2021-07-30
Latest Received Date:	N/A
Total Number of Reports:	802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000960073	0	2021-07-22	2021-07-22	Community		Spontaneous	Nurse

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
81 Years	Female	64 Inch	137 Pound	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Parenteral		Once	78.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Retinal vascular thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000960074	0	2021-07-22	2021-07-22	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
74 Years	Male	75 Inch	110 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR			Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Lacrimation increased	v.24.1	
Photophobia	v.24.1	
Vision blurred	v.24.1	68 Days
Visual impairment	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:07:47 AM
Initial Received Date:	2021-06-16 to 2021-07-30
Latest Received Date:	N/A
Total Number of Reports:	802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000960075	0	2021-07-22	2021-07-22	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR					COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Menstruation delayed	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000960076	0	2021-07-22	2021-07-22	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SUSPENSION INTRAMUSCULAR			Once		
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR			Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Amenorrhoea	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000960077	0	2021-07-22	2021-07-22	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Bedridden	v.24.1	
Decreased appetite	v.24.1	
Dizziness	v.24.1	
Eye pain	v.24.1	
Feeling abnormal	v.24.1	
Headache	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Insomnia	v.24.1	
Irritability	v.24.1	
Migraine	v.24.1	
Nausea	v.24.1	
Neck pain	v.24.1	
Pain	v.24.1	
Rhinorrhoea	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000960078	0	2021-07-22	2021-07-22	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
35 Years	Female		145 Pound	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
DEXILANT	Concomitant	CAPSULE, DELAYED RELEASE					
MIDOL NOS	Concomitant	Tablets					
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect					84.0 Days	COVID-19 immunisation
TYLENOL	Concomitant	ELIXIR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal distension	v.24.1	
Abdominal pain upper	v.24.1	
Duodenogastric reflux	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dysmenorrhoea	v.24.1	
Headache	v.24.1	
Heavy menstrual bleeding	v.24.1	
Menstruation delayed	v.24.1	
Pain	v.24.1	
Pain management	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:07:47 AM
Initial Received Date:	2021-06-16 to 2021-07-30
Latest Received Date:	N/A
Total Number of Reports:	802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000960079	0	2021-07-22	2021-07-22	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID VACCINE	Suspect	SOLUTION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Product administered at inappropriate site	v.24.1	
Product administration error	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000960080	0	2021-07-22	2021-07-22	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:		Disability:	Yes	Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	

Patient Information

Age	Gender	Height	Weight	Report Outcome
63 Years	Female	65 Inch	80 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETAMINOPHEN	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once	64.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bell's palsy	v.24.1	
Oral herpes	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000960083	0	2021-07-22	2021-07-22	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
75 Years	Female	65 Inch	135 Pound	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID VACCINE	Suspect	SOLUTION INTRAMUSCULAR					COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Insomnia	v.24.1	61 Days
Pain in extremity	v.24.1	61 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000960088	0	2021-07-22	2021-07-22	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
17 Years	Female	159 Centimeter	140 Pound	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Loss of consciousness	v.24.1	
Seizure	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000960216	0	2021-07-23	2021-07-23	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
75 Years	Male	73 Inch	184 Pound	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Balance disorder	v.24.1	
Blood pressure decreased	v.24.1	
Decreased appetite	v.24.1	
Dizziness	v.24.1	
Hyperhidrosis	v.24.1	
Night sweats	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000960219	0	2021-07-23	2021-07-23	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
83 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular				COVID-19 prophylaxis
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect						COVID-19 prophylaxis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Inflammation	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Mobility decreased	v.24.1	
Wrong technique in product usage process	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000960220	0	2021-07-23	2021-07-23	Hospital		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
35 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Subcutaneous		Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Myocarditis	v.24.1	3 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000960222	0	2021-07-23	2021-07-23	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
24 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Lymphadenopathy	v.24.1	
Musculoskeletal stiffness	v.24.1	
Oropharyngeal pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000960224	0	2021-07-23	2021-07-23	Community		Spontaneous	Pharmacist

Serious report?	Death:		Disability:	Yes	Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
65 Years	Female	67 Inch	133 Pound	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COLCHICINE	Concomitant	Tablets					
FOLIC ACID	Concomitant	NOT SPECIFIED					
METHOTREXATE	Concomitant	NOT SPECIFIED	Intrathecal				
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect				Once		COVID-19 immunisation
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect				Once		COVID-19 immunisation
NAPROXEN	Concomitant	NOT SPECIFIED					
PANTOPRAZOLE	Concomitant	NOT SPECIFIED					
PREDNISONE	Concomitant	NOT SPECIFIED					
VITAMIN D	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dyspnoea	v.24.1	
Gait inability	v.24.1	
Loss of personal independence in daily activities	v.24.1	
Pain in extremity	v.24.1	
Pericarditis	v.24.1	
Rheumatoid arthritis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000960225	0	2021-07-25	2021-07-25	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
33 Years	Female	167 Centimeter	62 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	0.5 ml			COVID-19 immunisation
LINESSA 28	Suspect	Tablets	Oral	1.0 Dosage forms	1 every 1 Days	9.0 Days	Contraception

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.24.1	
Hemiparesis	v.24.1	
Memory impairment	v.24.1	
Mobility decreased	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Motor dysfunction	v.24.1	
Paraesthesia	v.24.1	
Photophobia	v.24.1	
Transient ischaemic attack	v.24.1	7 Days
Visual impairment	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000960226	0	2021-07-23	2021-07-23	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
16 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR			Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest discomfort	v.24.1	
Myocarditis	v.24.1	
Palpitations	v.24.1	
Troponin increased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000960227	0	2021-07-23	2021-07-23	Hospital		Spontaneous	Consumer/other non health professional

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
53 Years	Male		79 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular		Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Angioedema	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000960229	0	2021-07-25	2021-07-25	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
50 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Eye irritation	v.24.1	
Feeling jittery	v.24.1	
Headache	v.24.1	
Hypertension	v.24.1	
Rash	v.24.1	
Thyroiditis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000960230	0	2021-07-23	2021-07-23	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
72 Years	Female	64 Inch	150 Pound	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular				COVID-19 prophylaxis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Musculoskeletal chest pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000960234	0	2021-07-23	2021-07-23	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
DOXYCYCLINE	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR			Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Muscular weakness	v.24.1	
Paraesthesia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000960235	0	2021-07-23	2021-07-23	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	000963368

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Deep vein thrombosis	v.24.1	
Thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000960414	0	2021-07-26	2021-07-26	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
57 Years	Male	183 Centimeter	90 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASA	Concomitant	NOT SPECIFIED					
ATORVASTATIN	Concomitant	NOT SPECIFIED					
BISOPROLOL FUMARATE	Concomitant	Tablets					
EZETIMIBE	Concomitant	Tablets					
PERINDOPRIL	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Bone pain	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Swelling	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000960415	0	2021-07-26	2021-07-26	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
29 Years	Male	178 Centimeter	97 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Exercise tolerance decreased	v.24.1	
Fatigue	v.24.1	
Muscular weakness	v.24.1	
Neck pain	v.24.1	
Pain	v.24.1	
Pain in extremity	v.24.1	
Somnolence	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Vaccination site pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000960416	0	2021-07-26	2021-07-26	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
50 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		COVID-19 prophylaxis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Insomnia	v.24.1	11 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000960418	0	2021-07-26	2021-07-26	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
46 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
IRON	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blister	v.24.1	
Eye pain	v.24.1	
Eye swelling	v.24.1	
Facial pain	v.24.1	
Herpes zoster	v.24.1	
Malaise	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Swelling face	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000960420	0	2021-07-26	2021-07-26	Community		Spontaneous	Other health professional

Serious report?	Death:		Disability:	Yes	Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	

Patient Information

Age	Gender	Height	Weight	Report Outcome
68 Years	Female	62 Inch	207 Pound	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR			Once		
TRESIBA	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Injection site pain	v.24.1	
Muscle spasms	v.24.1	
Myalgia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000960422	0	2021-07-26	2021-07-26	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
60 Years	Female	62 Inch	180 Pound	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CODEINE	Concomitant	NOT SPECIFIED	Unknown				
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Once		COVID-19 immunisation
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Acne	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Fatigue	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000960639	0	2021-07-27	2021-07-27	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
68 Years	Female			Recovered/resolved with sequelae

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MULTIVITAMINE(S)	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					
VITAMIN D	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Herpes zoster	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000960641	0	2021-07-27	2021-07-27	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
48 Years	Female	165 Centimeter	94 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ANTIBIOTIC NOS	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Disease recurrence	v.24.1	
Joint swelling	v.24.1	2 Days
Loss of personal independence in daily activities	v.24.1	
Movement disorder	v.24.1	
Musculoskeletal stiffness	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pain in extremity	v.24.1	
Paraesthesia	v.24.1	
Peripheral swelling	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000960647	0	2021-07-27	2021-07-27	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect				Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Ear discomfort	v.24.1	
Hyperacusis	v.24.1	
Migraine	v.24.1	
Vibratory sense increased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000960648	0	2021-07-27	2021-07-27	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
70 Years				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Back pain	v.24.1	
Herpes zoster	v.24.1	
Pain	v.24.1	
Pelvic pain	v.24.1	
Rash vesicular	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000960663	0	2021-07-28	2021-07-28	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood iron decreased	v.24.1	
Decreased activity	v.24.1	
Heavy menstrual bleeding	v.24.1	
Impaired quality of life	v.24.1	
Loss of personal independence in daily activities	v.24.1	
Physical disability	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Polymenorrhoea	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000960665	0	2021-07-27	2021-07-27	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
54 Years	Female	162 Centimeter	90 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE	Suspect		Intramuscular	0.5 ml			Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Back pain	v.24.1	
Chills	v.24.1	
Fatigue	v.24.1	
Muscle spasms	v.24.1	
Myalgia	v.24.1	
Pain in extremity	v.24.1	
Pyrexia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000960897	0	2021-07-28	2021-07-28	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
67 Years	Male	66 Inch	140 Pound	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect				Once	81.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Back pain	v.24.1	
Condition aggravated	v.24.1	
Pain in extremity	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000960898	0	2021-07-28	2021-07-28	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
54 Years	Female	168 Centimeter	61 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				COVID-19

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.24.1	
Dyspnoea	v.24.1	
Heart rate decreased	v.24.1	
Heart rate increased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000960900	0	2021-07-28	2021-07-28	Community		Spontaneous	Pharmacist

Serious report?	Death:		Disability:		Congenital Anomaly:	
Not Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
42 Years	Female			Recovering/resolving

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular		Once		COVID-19 immunisation
VISANNE	Concomitant	Tablets					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Palmar-plantar erythrodysaesthesia syndrome	v.24.1	
Urticaria	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:07:47 AM
Initial Received Date:	2021-06-16 to 2021-07-30
Latest Received Date:	N/A
Total Number of Reports:	802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000960903	0	2021-07-28	2021-07-28	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID 19 VACCINE - MANUFACTURER UNKNOWN	Suspect						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Back pain	v.24.1	
Herpes zoster	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000960904	0	2021-07-28	2021-07-28	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR			Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Muscle spasms	v.24.1	
Tremor	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000960906	0	2021-07-28	2021-07-28	Community		Spontaneous	Physician

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
72 Years	Male			Recovering/resolving

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CRESTOR	Concomitant	Tablets					
JARDIANCE	Concomitant						
METFORMIN	Concomitant	Tablets					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR					COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Radiculitis brachial	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000960911	0	2021-07-28	2021-07-28	Community		Spontaneous	Physician

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
60 Years	Female	60 Inch	54 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
GABAPENTIN	Concomitant	NOT SPECIFIED					
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect						
SYMBICORT	Concomitant	Powder	Inhalation				
SYNTHROID	Concomitant	NOT SPECIFIED					
VENTOLIN	Concomitant	NOT SPECIFIED					
VIMOVO MODIFIED-RELEASE TABLET	Concomitant	TABLET (DELAYED AND IMMEDIATE RELEASE)					
VITAMIN D	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Chest pain	v.24.1	
Hypoaesthesia	v.24.1	
Inflammation	v.24.1	
Myalgia	v.24.1	
Pain in extremity	v.24.1	
Paraesthesia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000961129	0	2021-07-29	2021-07-29	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
65 Years	Male	70 Inch	203 Pound	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Parenteral	0.3 ml	Once		COVID-19 prophylaxis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.24.1	
Feeling abnormal	v.24.1	
Injection site pain	v.24.1	
Pruritus	v.24.1	
Pyrexia	v.24.1	4 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000961136	0	2021-07-29	2021-07-29	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
45 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ADVIL	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Once		COVID-19 immunisation
PREDNISONE	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenopia	v.24.1	
Blindness unilateral	v.24.1	
Fatigue	v.24.1	
Feeling abnormal	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.24.1	
Impaired work ability	v.24.1	
Optic neuritis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000961137	0	2021-07-30	2021-07-30	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
48 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Ear pain	v.24.1	82 Days
Hypoaesthesia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000961289	0	2021-07-30	2021-07-30	Hospital		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
30 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.24.1	
Nausea	v.24.1	
Pericarditis	v.24.1	
Pyrexia	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000961290	0	2021-07-30	2021-07-30	Hospital		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
78 Years	Female	163 Centimeter	87 Kilogram	Recovering/resolving

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID VACCINE	Suspect	SOLUTION INTRAMUSCULAR	Subcutaneous		Once		
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Subcutaneous		Once		
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Subcutaneous				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bronchospasm	v.24.1	3 Days
Oedema peripheral	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000961291	0	2021-07-30	2021-07-30	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
43 Years	Female	173 Centimeter	79 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dysmenorrhoea	v.24.1	
Heavy menstrual bleeding	v.24.1	
Menstruation delayed	v.24.1	
Menstruation irregular	v.24.1	7 Days
Polymenorrhoea	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000961292	0	2021-07-30	2021-07-30	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
58 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR		1.0 Dosage forms			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest discomfort	v.24.1	
Dyspnoea	v.24.1	
Pericardial effusion	v.24.1	
Pericarditis	v.24.1	
Tachycardia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:07:47 AM
Initial Received Date:	2021-06-16 to 2021-07-30
Latest Received Date:	N/A
Total Number of Reports:	802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000961296	0	2021-07-30	2021-07-30	Hospital		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
22 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000961297	0	2021-07-30	2021-07-30	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
20 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.24.1	
Chills	v.24.1	
Myocarditis	v.24.1	
Pericarditis	v.24.1	
Pyrexia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:07:47 AM
Initial Received Date:	2021-06-16 to 2021-07-30
Latest Received Date:	N/A
Total Number of Reports:	802 Report(s)

Report Information

***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000961300	0	2021-07-30	2021-07-30	Hospital		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
70 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Aphasia	v.24.1	
Facial paralysis	v.24.1	
Urinary incontinence	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000961301	0	2021-07-30	2021-07-30	Community		Spontaneous	Physician

Serious report?	Death:		Disability:		Congenital Anomaly:	
Not Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
53 Years	Female	65 Inch	154 Pound	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	0.5 ml	Once	13.0 Days	COVID-19 immunisation
SYNTHROID	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Urticaria	v.24.1	13 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000961302	0	2021-07-30	2021-07-30	Community		Spontaneous	Other health professional

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:	Yes	Hospitalization:	Yes	Other Medically Important Conditions:	

Patient Information

Age	Gender	Height	Weight	Report Outcome
45 Years	Female	64 Inch	154 Pound	Recovering/resolving

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Subcutaneous		1 every 1 Days		Visual impairment

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Vision blurred	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000961305	0	2021-07-30	2021-07-30	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR				73.0 Days	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood glucose decreased	v.24.1	
Decreased insulin requirement	v.24.1	
Pre-existing condition improved	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000963368	0	2021-07-23	2021-07-23	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	000960235

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect						
XARELTO	Concomitant	Tablets					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Superficial vein thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000964354	0	2021-07-07	2021-07-07	MAH		Spontaneous	Consumer/other non health professional

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:	Yes	Other Medically Important Conditions:	

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female		65 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE	Suspect						
CHLORHEXIDINE	Suspect	MOUTHWASH					
DESLORATADINE	Concomitant	Tablets					
ESOMEPRAZOLE	Concomitant	NOT SPECIFIED	Unknown				
FLIXONASE NASAL SPRAY	Concomitant						
GAVISCON	Concomitant	NOT SPECIFIED					
LIDOCAINE HYDROCHLORIDE INJECTION SINGLE USE	Concomitant	SOLUTION BLOCK/INFILTRATION					
PARACETAMOL/PSEUDOEPHEDRINE HCL	Concomitant	NOT SPECIFIED	Unknown				

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PREGABALIN (MANUFACTURER UNKNOWN)	Concomitant						
SAVLON HOSPITAL CONCENTRATE	Suspect	LIQUID TOPICAL					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Aphthous ulcer	v.24.1	
Hypersensitivity	v.24.1	
Lymph node pain	v.24.1	
Paraesthesia	v.24.1	
Seizure	v.24.1	
Skin ulcer	v.24.1	
Tachycardia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04297041	0	2021-06-16	2021-06-16	MAH	2021654702	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypoaesthesia	v.24.1	
Palpitations	v.24.1	
Uterine haemorrhage	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04297064	0	2021-06-16	2021-06-16	MAH	2021655062	Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blindness transient	v.24.1	
Ophthalmic migraine	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04297166	1	2021-06-16	2021-07-13	MAH	2021684280	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
83 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ADVAIR	Concomitant	NOT SPECIFIED	Inhalation				Asthma
ALVESCO	Concomitant	AEROSOL, METERED DOSE	Inhalation				Asthma
ATORVASTATIN	Concomitant		Oral				Blood cholesterol
DILTIAZEM HYDROCHLORIDE	Concomitant		Oral	120.0 Milligram			Hypertension
DUPILUMAB	Concomitant		Intramuscular				Eczema
ELIQUIS FILM COATED	Concomitant	Tablets	Oral				Pulmonary embolism
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	4.0 Days	COVID-19 immunisation

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
SPIRIVA	Concomitant	NOT SPECIFIED	Inhalation				Asthma
VENTOLIN [SALBUTAMOL]	Concomitant		Inhalation				Asthma

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bell's palsy	v.24.1	
Ear pain	v.24.1	
Inappropriate schedule of product administration	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04297578	4	2021-06-16	2021-08-21	MAH	2021634557	Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
55 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_04357848
Linked	E2B_04357848
Linked	E2B_04357848
Linked	E2B_04357848
Linked	
Linked	E2B_04357848
Linked	E2B_04357848

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ANGELICA ACUTILOBA	Concomitant		Oral				Menopause
CONSTELLA	Concomitant	Capsules	Oral	145.0 Milligram	As required		Constipation
DEXILANT	Concomitant	CAPSULE, DELAYED RELEASE		60.0 Milligram			Gastrooesophageal reflux disease
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
SERC [THIORIDAZINE]	Concomitant		Oral	24.0 Milligram	As required		Vertigo
TYLENOL	Concomitant	NOT SPECIFIED					Headache
ZOMIG	Concomitant	NOT SPECIFIED	Oral	2.5 Milligram	every 1 Days		Migraine

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood pressure diastolic decreased	v.24.1	
Blood pressure fluctuation	v.24.1	
Disease recurrence	v.24.1	
Dizziness	v.24.1	
Headache	v.24.1	6 Days
Headache	v.24.1	9 Days
Heavy menstrual bleeding	v.24.1	
Infection	v.24.1	1 Months
Pain in extremity	v.24.1	6 Days
Pyrexia	v.24.1	1 Months
Therapeutic response unexpected	v.24.1	
Vaccination site pain	v.24.1	6 Days
Vertigo	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04297582	1	2021-06-16	2021-08-02	MAH	2021641555	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
59 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
LEVOTHYROXINE SODIUM	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Central nervous system inflammation	v.24.1	
Decreased appetite	v.24.1	
Gastrointestinal sounds abnormal	v.24.1	
Headache	v.24.1	
Muscle spasms	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Muscular weakness	v.24.1	
Pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04297659	0	2021-06-16	2021-06-16	MAH	CA2021AMR127469	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
73 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	
Linked	E2B_05374755
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				Prophylaxis
MEPOLIZUMAB	Suspect		Subcutaneous	100.0 Milligram			Asthma

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cataract	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04297729	2	2021-06-16	2021-07-30	MAH	2021664767	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
69 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation
XELJANZ	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Rheumatoid arthritis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04297767	0	2021-06-16	2021-06-16	MAH	2021641745	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
22 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
VISANNE	Concomitant	Tablets					
WELBUTRIN	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Gait disturbance	v.24.1	
Muscular weakness	v.24.1	
Pain	v.24.1	
Painful respiration	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04297812	0	2021-06-16	2021-06-16	MAH	20210619373	Study	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
42 Years	Female		83 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	
Linked	
Linked	E2B_04491983
Linked	E2B_04491983

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				COVID-19 prophylaxis
REMICADE	Suspect	POWDER FOR SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	400.0 Milligram	1 every 6 Weeks		Crohn's disease

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal distension	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Flatulence	v.24.1	
Respiratory tract infection	v.24.1	-142

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04297825	1	2021-06-16	2021-06-23	MAH	2021A526238	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bedridden	v.24.1	
Dyspnoea	v.24.1	
Hypertension	v.24.1	
Illness	v.24.1	
Productive cough	v.24.1	
Renal disorder	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04298649	1	2021-06-16	2021-07-29	MAH	2021641145	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
62 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CETIRIZINE HYDROCHLORIDE	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Atrial fibrillation	v.24.1	
Disease recurrence	v.24.1	
Inappropriate schedule of product administration	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04298673	1	2021-06-16	2021-07-28	MAH	2021655018	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
18 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Loss of consciousness	v.24.1	
Unresponsive to stimuli	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04298798	1	2021-06-16	2021-07-28	MAH	2021641104	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
56 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ELIQUIS FILM COATED	Concomitant	Tablets					
ERGOCALCIFEROL	Concomitant						
ESCITALOPRAM	Concomitant	Tablets					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
ROSUVASTATIN CALCIUM	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.24.1	-114
Mobility decreased	v.24.1	-114

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Nausea	v.24.1	-114
Vomiting	v.24.1	-114

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04298852	1	2021-06-16	2021-06-30	MAH	2021654678	Spontaneous	Physician

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
83 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CANDESARTAN	Concomitant		Oral				Hypertension
D-ALPHA TOCOPHEROL/ERGOCALCIFEROL/FOLIC ACID/FOLIC ACID/VITAMIN A/VITAMIN C	Concomitant						
GLUCOSAMINE	Concomitant	NOT SPECIFIED					
MAGNESIUM	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
ROSUVASTATIN CALCIUM	Concomitant		Oral				Blood cholesterol increased

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
TURMERIC [CURCUMA LONGA]	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Fatigue	v.24.1	
Insomnia	v.24.1	
Loss of personal independence in daily activities	v.24.1	
Muscular weakness	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04303573	1	2021-06-17	2021-07-26	MAH	2021649042	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
92 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bradycardia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04303614	0	2021-06-17	2021-06-17	MAH	2021671632	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
63 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CURCUMA	Concomitant	Capsule					
CYANOCOBALAMIN	Concomitant						
FOLIC ACID	Concomitant	NOT SPECIFIED					
METHOTREXATE SODIUM	Concomitant						Systemic lupus erythematosus
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
VITAMIN D3	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain	v.24.1	
Agitation	v.24.1	
Asthenia	v.24.1	
Balance disorder	v.24.1	
Chills	v.24.1	
Disturbance in attention	v.24.1	
Dizziness	v.24.1	
Eye irritation	v.24.1	
Faeces soft	v.24.1	
Fatigue	v.24.1	
Feeling hot	v.24.1	
Headache	v.24.1	
Hyperhidrosis	v.24.1	
Hypoaesthesia	v.24.1	1 Days
Insomnia	v.24.1	
Myalgia	v.24.1	
Nausea	v.24.1	
Palpitations	v.24.1	
Paraesthesia	v.24.1	1 Days
Pollakiuria	v.24.1	
Swelling	v.24.1	
Tinnitus	v.24.1	
Vaccination site pain	v.24.1	3 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04303632	0	2021-06-17	2021-06-17	MAH	2021649038	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
43 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Crying	v.24.1	
Depression	v.24.1	
Emotional disorder	v.24.1	
Fatigue	v.24.1	
Haemorrhage	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Heavy menstrual bleeding	v.24.1	
Hot flush	v.24.1	
Insomnia	v.24.1	
Menstrual disorder	v.24.1	
Muscle spasms	v.24.1	
Pyrexia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04303678	1	2021-06-17	2021-07-26	MAH	2021649905	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
39 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Myocarditis	v.24.1	
Pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:07:47 AM
Initial Received Date:	2021-06-16 to 2021-07-30
Latest Received Date:	N/A
Total Number of Reports:	802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04303897	1	2021-06-17	2021-06-30	MAH	2021701326	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
30 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Back pain	v.24.1	-113
Fatigue	v.24.1	-110
Hot flush	v.24.1	-154
Hypoaesthesia	v.24.1	-90
Muscular weakness	v.24.1	-90
Musculoskeletal stiffness	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Nausea	v.24.1	-108
Pain in extremity	v.24.1	-113
Peripheral swelling	v.24.1	-90
Skin lesion	v.24.1	-90

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:07:47 AM
Initial Received Date:	2021-06-16 to 2021-07-30
Latest Received Date:	N/A
Total Number of Reports:	802 Report(s)

Report Information

***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04304113	0	2021-06-17	2021-06-17	MAH	2021298223	Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
48 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dehydration	v.24.1	
Diarrhoea	v.24.1	
Muscle spasms	v.24.1	
Nausea	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:07:47 AM
Initial Received Date:	2021-06-16 to 2021-07-30
Latest Received Date:	N/A
Total Number of Reports:	802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04304251	0	2021-06-17	2021-06-17	MAH	2021670534	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
75 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ATENOLOL	Concomitant	Tablets	Oral	50.0 Milligram	2 every 1 Days		Palpitations
CYANOCOBALAMIN	Concomitant		Oral				
DILTIAZEM	Concomitant		Oral	240.0 Milligram	every 1 Days		Blood pressure abnormal
ESCITALOPRAM	Concomitant	Tablets	Oral	10.0 Milligram	every 1 Days		Depression
FLUTICASONE	Concomitant		Unknown				Asthma
LEVOTHYROXINE SODIUM	Concomitant	NOT SPECIFIED	Oral	0.1 Milligram	every 1 Days		Thyroid neoplasm
OLMESARTAN	Concomitant		Oral	40.0 Milligram	every 1 Days		Blood pressure abnormal

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
ROSUVASTATIN	Concomitant	NOT SPECIFIED	Oral	5.0 Milligram	every 1 Days		Prophylaxis
SALBUTAMOL SULFATE	Concomitant			100.0 Microgram			Asthma
TRAZODONE	Concomitant		Oral	50.0 Milligram	every 1 Days		Sleep disorder
VITAMIN D3	Concomitant	Capsules	Oral				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal discomfort	v.24.1	2 Months
Bone pain	v.24.1	
Burning sensation	v.24.1	1 Months
Diarrhoea	v.24.1	1 Months
Fatigue	v.24.1	
Haematochezia	v.24.1	-90
Headache	v.24.1	
Myalgia	v.24.1	
Pain in extremity	v.24.1	
Peripheral swelling	v.24.1	1 Months
Pruritus	v.24.1	1 Months
Rash	v.24.1	1 Months
Throat irritation	v.24.1	2 Months

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:07:47 AM
Initial Received Date:	2021-06-16 to 2021-07-30
Latest Received Date:	N/A
Total Number of Reports:	802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04304468	1	2021-06-17	2021-08-02	MAH	2021404666	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
64 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	2 Months
Diarrhoea	v.24.1	1 Days
Dizziness	v.24.1	1 Days
Fatigue	v.24.1	2 Months
Hypersensitivity	v.24.1	
Malaise	v.24.1	2 Months

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Vomiting	v.24.1	2 Hours

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:07:47 AM
Initial Received Date:	2021-06-16 to 2021-07-30
Latest Received Date:	N/A
Total Number of Reports:	802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04304553	1	2021-06-17	2021-06-30	MAH	2021677008	Spontaneous	Pharmacist

Serious report?	Death:	Disability:	Congenital Anomaly:
Serious	Yes	No	No
	Life Threatening: No	**Hospitalization:** No	**Other Medically Important Conditions:** No

Patient Information

Age	Gender	Height	Weight	Report Outcome
95 Years	Male			Fatal

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Months	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Death	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:07:47 AM
Initial Received Date:	2021-06-16 to 2021-07-30
Latest Received Date:	N/A
Total Number of Reports:	802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04305755	0	2021-06-18	2021-06-18	MAH	BL-2021-008367	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
58 Years	Female		70 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
APO-MEDROXY	Concomitant	Tablets		2.5 Milligram			Product used for unknown indication
CONTRAVE	Suspect	TABLET (EXTENDED-RELEASE)	Oral				Weight control
CONTRAVE	Suspect	Tablet	Oral	2.0 Dosage forms	1 every 12 Hours	2.0 Years	Weight control
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Unknown			1.0 Months	Product used for unknown indication
LUPIN-ESTRADIOL	Concomitant	Tablets		1.0 Milligram			Product used for unknown indication

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PANTOPRAZOLE	Concomitant	NOT SPECIFIED		40.0 Milligram			Product used for unknown indication
SYNTHROID	Concomitant	NOT SPECIFIED	Oral	0.25 Milligram	1 every 1 Days		Hypothyroidism
VITAMIN D	Concomitant	NOT SPECIFIED					Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood glucose decreased	v.24.1	
Constipation	v.24.1	
Drug ineffective	v.24.1	
Feeling abnormal	v.24.1	
Lymphadenopathy	v.24.1	
Nausea	v.24.1	
Swelling face	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04306976	1	2021-06-18	2021-07-01	MAH	2021353719	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
38 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypoaesthesia oral	v.24.1	
Numb chin syndrome	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04307206	1	2021-06-18	2021-08-02	MAH	2021664871	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
36 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pancreatitis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04307209	2	2021-06-18	2021-08-20	MAH	2021655109	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
47 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Atrial fibrillation	v.24.1	
Heart rate irregular	v.24.1	
Inappropriate schedule of product administration	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04307260	2	2021-06-18	2021-08-02	MAH	2021655778	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
36 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
METOPROLOL	Concomitant		Oral		2 every 1 Days		Supraventricular tachycardia
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
VENLAFAXINE	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	
Tachycardia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04307265	0	2021-06-18	2021-06-18	MAH	2021655758	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
39 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
SERTRALINE	Concomitant	Capsules		50.0 Milligram			
TETANUS VACCINE	Concomitant					1.0 Days	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypoaesthesia	v.24.1	
Loss of consciousness	v.24.1	
Syncope	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04307498	1	2021-06-18	2021-06-30	MAH	2021670649	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
64 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
SYNTHROID	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest discomfort	v.24.1	1 Months
Dyspnoea	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04307643	2	2021-06-18	2021-08-20	MAH	2021665409	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
32 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Months	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Heavy menstrual bleeding	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04307831	1	2021-06-18	2021-06-23	MAH	2021656404	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
27 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest discomfort	v.24.1	
Insomnia	v.24.1	
Palpitations	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04307840	0	2021-06-18	2021-06-18	MAH	2021677922	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
20 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Months	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pulmonary embolism	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04307845	1	2021-06-18	2021-07-08	MAH	2021665377	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
34 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Confusional state	v.24.1	
Dizziness	v.24.1	
Dyspnoea	v.24.1	
Headache	v.24.1	
Hyperhidrosis	v.24.1	
Loss of consciousness	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Muscle spasms	v.24.1	
Palpitations	v.24.1	
Speech disorder	v.24.1	
Syncope	v.24.1	
Vision blurred	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04307846	2	2021-06-18	2021-07-29	MAH	2021656432	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Haematuria	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04307851	1	2021-06-18	2021-07-22	MAH	2021656142	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
36 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Back pain	v.24.1	
Hypoaesthesia	v.24.1	
Muscle spasms	v.24.1	
Muscular weakness	v.24.1	
Paraesthesia	v.24.1	
Vaccination site pain	v.24.1	3 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04307866	0	2021-06-18	2021-06-18	MAH	2021656539	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
52 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	
Headache	v.24.1	
Insomnia	v.24.1	
Pain in extremity	v.24.1	
Tinnitus	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04307905	2	2021-06-18	2021-08-02	MAH	2021654920	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
39 Years	Male	15 Centimeter	83 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal distension	v.24.1	
Constipation	v.24.1	
Depression	v.24.1	
Fatigue	v.24.1	
Feeling abnormal	v.24.1	
Flatulence	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Gastrointestinal hypomotility	v.24.1	
Insomnia	v.24.1	
Weight decreased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04307958	0	2021-06-18	2021-06-18	MAH	2021665318	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
15 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Syncope	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04308014	1	2021-06-18	2021-07-30	MAH	2021656826	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
64 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
METFORMIN HYDROCHLORIDE	Concomitant			2000.0 Milligram			
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
RAMIPRIL	Concomitant	NOT SPECIFIED		11.25 Milligram			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cerebrovascular accident	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04309373	1	2021-06-18	2021-08-02	MAH	2021677276	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Disease recurrence	v.24.1	
Nervous system disorder	v.24.1	
Vascular rupture	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04310183	1	2021-06-19	2021-07-15	MAH	2212481	Study	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
50 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETAMINOPHEN	Concomitant	NOT SPECIFIED	Unknown				
BACLOFEN	Concomitant	NOT SPECIFIED	Unknown				Muscle spasms
COVID-19 VACCINE	Suspect		Unknown				Product used for unknown indication
MELATONIN	Concomitant	NOT SPECIFIED	Unknown				
OCRELIZUMAB	Suspect		Intravenous (not otherwise specified)	300.0 Milligram	1 every 2 Weeks		Primary progressive multiple sclerosis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	
Initial insomnia	v.24.1	
Limb immobilisation	v.24.1	
Poor quality sleep	v.24.1	
Pyrexia	v.24.1	
Sensory loss	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04310370	0	2021-06-19	2021-06-19	MAH	2021348913	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
43 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.24.1	1 Hours
Ear discomfort	v.24.1	
Erythema	v.24.1	1 Hours

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04310854	1	2021-06-20	2021-07-01	MAH	2021665700	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
37 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Angina pectoris	v.24.1	31 Hours
Arthralgia	v.24.1	1 Months
Myocarditis	v.24.1	28 Hours

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04310937	0	2021-06-21	2021-06-21	MAH	2021671928	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
38 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.24.1	
Dry mouth	v.24.1	
Fatigue	v.24.1	
Feeling abnormal	v.24.1	
Headache	v.24.1	
Injected limb mobility decreased	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Nausea	v.24.1	
Pain in extremity	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04311961	3	2021-06-21	2021-10-07	MAH	CA2021AMR104847	Study	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
92 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_03420890
Linked	
Linked	E2B_05394747
Linked	
Linked	E2B_03420890
Linked	
Linked	E2B_03700662
Linked	
Linked	E2B_03420890
Linked	
Linked	E2B_03420890
Linked	
Linked	E2B_03420890
Linked	E2B_03700662

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				Product used for unknown indication, COVID-19 prophylaxis
COVID-19 VACCINE	Suspect		Unknown				Product used for unknown indication, COVID-19 prophylaxis
MEPOLIZUMAB	Suspect		Subcutaneous	100.0 Milligram			Asthma
MEPOLIZUMAB	Suspect	Solution for injection in pre-filled syringe	Subcutaneous	100.0 Milligram			Asthma

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood pressure increased	v.24.1	
Cellulitis	v.24.1	
Fall	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Incision site discharge	v.24.1	
Limb injury	v.24.1	
Ocular hyperaemia	v.24.1	
Squamous cell carcinoma	v.24.1	
Suture insertion	v.24.1	
Wheezing	v.24.1	
Wound infection	v.24.1	
Wound treatment	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04313332	2	2021-06-21	2021-09-27	MAH	20210509993	Study	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
56 Years	Male		100 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	
Linked	E2B_03622965
Linked	
Linked	
Linked	E2B_03622965
Linked	
Linked	
Linked	E2B_03622965
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				COVID-19 prophylaxis

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PREDNISONE	Concomitant	NOT SPECIFIED	Oral				Product used for unknown indication
PREDNISONE	Concomitant	Capsules	Oral	4.0 Milligram			Product used for unknown indication
STELARA	Suspect	Solution for injection in pre-filled syringe	Subcutaneous	90.0 Milligram	1 every 4 Weeks		Colitis ulcerative
STELARA	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous	90.0 Milligram	1 every 8 Weeks		Colitis ulcerative

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain	v.24.1	-106
Defaecation urgency	v.24.1	
Diarrhoea	v.24.1	-111
Eructation	v.24.1	
Flatulence	v.24.1	
Frequent bowel movements	v.24.1	
Haematochezia	v.24.1	-90
Off label use	v.24.1	
Pain in jaw	v.24.1	
Product use issue	v.24.1	
Toothache	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04313965	0	2021-06-21	2021-06-21	MAH	2021671904	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
48 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETYLSALICYLIC ACID	Concomitant						
METFORMIN	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	3 Days
Axillary pain	v.24.1	3 Days
Breast pain	v.24.1	5 Days
Cardiac disorder	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cardiac flutter	v.24.1	5 Days
Chest discomfort	v.24.1	5 Days
Heart rate increased	v.24.1	3 Days
Painful respiration	v.24.1	128 Hours

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04313971	1	2021-06-21	2021-07-26	MAH	2021658650	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
64 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETYLSALICYLIC ACID	Concomitant		Oral		every 1 Days		
APO METOPROLOL	Concomitant	Tablets	Oral	100.0 Milligram	2 every 1 Days		
ATORVASTATIN	Concomitant		Oral	40.0 Milligram	every 1 Days		
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
RAMIPRIL	Concomitant		Oral	5.0 Milligram	every 1 Days		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Diarrhoea haemorrhagic	v.24.1	
Epistaxis	v.24.1	1 Days

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Frequent bowel movements	v.24.1	
Haematemesis	v.24.1	
Haemoglobin decreased	v.24.1	
Haemorrhage	v.24.1	1 Months
Hypotension	v.24.1	
Syncope	v.24.1	
Thrombosis	v.24.1	1 Months

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04313983	0	2021-06-21	2021-06-21	MAH	2021671860	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
25 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
WELLBUTRIN	Concomitant	TABLET (EXTENDED-RELEASE)					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Condition aggravated	v.24.1	
Dermatitis exfoliative	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04314005	1	2021-06-21	2021-07-27	MAH	2021676769	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
40 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anxiety	v.24.1	
Depressed mood	v.24.1	
Facial paralysis	v.24.1	
Feeling abnormal	v.24.1	
Feeling cold	v.24.1	
Pain	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Road traffic accident	v.24.1	
Vaccination site movement impairment	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04314015	0	2021-06-21	2021-06-21	MAH	2021664830	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
24 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Appendicitis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04317507	6	2021-06-22	2021-09-20	MAH	CA2021AMR116452	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
83 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ATORVASTATIN	Concomitant	Tablets	Unknown				Product used for unknown indication
CALCIUM	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication
COVID-19 VACCINE	Suspect		Unknown				Product used for unknown indication, COVID-19 prophylaxis
COVID-19 VACCINE	Suspect		Unknown				Product used for unknown indication, COVID-19 prophylaxis

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
METFORMIN	Concomitant		Unknown				Product used for unknown indication
VERAPAMIL	Concomitant		Unknown				Product used for unknown indication
VITAMIN D3	Concomitant	Capsules	Unknown				Product used for unknown indication
ZEJULA	Suspect	Capsules	Unknown				Ovarian epithelial cancer recurrent, Malignant peritoneal neoplasm, Fallopian tube cancer
ZEJULA	Suspect	Capsules	Oral	300.0 Milligram	1 every 1 Days		Ovarian epithelial cancer recurrent, Malignant peritoneal neoplasm, Fallopian tube cancer
ZEJULA	Suspect	Capsules	Oral	200.0 Milligram	1 every 1 Days	28.0 Days	Ovarian epithelial cancer recurrent, Malignant peritoneal neoplasm, Fallopian tube cancer

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain upper	v.24.1	
Decreased appetite	v.24.1	
Dyspnoea	v.24.1	
Dyspnoea exertional	v.24.1	
Heart rate increased	v.24.1	
Lung disorder	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pain in extremity	v.24.1	
Weight decreased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04319479	1	2021-06-22	2021-07-05	MAH	20210620447	Study	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
8 Decade	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown			1.0 Days	COVID-19 prophylaxis
STELARA	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous	90.0 Milligram	1 every 8 Weeks		Crohn's disease

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Immune system disorder	v.24.1	
Pneumonia bacterial	v.24.1	0

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04320640	0	2021-06-22	2021-06-22	MAH	2021664933	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
44 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BETA-CAROTENE/BIOTIN/CALCIUM CARBONATE/CALCIUM D-PANTOTHENATE/CHROMIC CHLORIDE/COPPER SULFATE/D-ALPHA TOCOPHERYL ACETATE/FERROUS FUMARATE/FOLIC ACID/LYCOPENE/MAGNESIUM OXIDE/MANGANESE SULFATE/NICOTINAMIDE/POTASSIUM CHLORIDE/POTASSIUM IODIDE	Concomitant						

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
VITAMIN B COMPLEX	Concomitant						
VITAMIN C [ASCORBIC ACID]	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain	v.24.1	
Hepatitis	v.24.1	
Splenitis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04320658	0	2021-06-22	2021-06-22	MAH	2021665644	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
75 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ATORVASTATIN CALCIUM	Concomitant	Tablets					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
RAMIPRIL	Concomitant	NOT SPECIFIED					
VITAMINS NOS	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Ophthalmic herpes zoster	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04320664	1	2021-06-22	2021-08-02	MAH	2021682631	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
43 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
INFLIXIMAB	Concomitant		Intravenous (not otherwise specified)	400.0 Milligram			Psoriatic arthropathy
METHOTREXATE	Concomitant	NOT SPECIFIED	Subcutaneous	25.0 Milligram	1 every 1 Weeks		Psoriatic arthropathy
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal distension	v.24.1	
Abdominal pain upper	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Diarrhoea	v.24.1	
Haematochezia	v.24.1	
Sepsis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04320666	1	2021-06-22	2021-07-30	MAH	2021676514	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
66 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ALTACE	Concomitant	Capsules					
ATENOLOL	Concomitant	Tablets					
NIFEDIPINE	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Months	COVID-19 immunisation
RABEPRAZOLE	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Deafness neurosensory	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04320711	0	2021-06-22	2021-06-22	MAH	2021678014	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
34 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Haematochezia	v.24.1	
Inappropriate schedule of product administration	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04320765	1	2021-06-22	2021-07-29	MAH	2021708739	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
49 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cerebral haemorrhage	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04320798	1	2021-06-22	2021-08-18	MAH	2021734324	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Months	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Postmenopausal haemorrhage	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04320812	1	2021-06-22	2021-07-19	MAH	2021670996	Spontaneous	Physician

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
28 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bell's palsy	v.24.1	
Monocyte count increased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:07:47 AM
Initial Received Date:	2021-06-16 to 2021-07-30
Latest Received Date:	N/A
Total Number of Reports:	802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04320840	1	2021-06-22	2021-07-02	MAH	2021677839	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
68 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETYLSALICYLIC ACID	Concomitant		Oral	40.0 Milligram	1 every 1 Days		Prophylaxis
AMITRIPTYLINE	Concomitant		Oral	20.0 Milligram	1 every 1 Days		Fibromyalgia
CANNABIS SATIVA	Concomitant		Oral				Fibromyalgia
FLOVENT	Concomitant	NOT SPECIFIED			As required		Asthma
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
REPATHA 1 ML SINGLE USE PREFILLED SYRINGE AND AUTOINJECTOR	Concomitant	SOLUTION SUBCUTANEOUS	Oral	120.0 Milligram	1 every 1 Months		Hypercholesterolaemia
ZOPICLONE	Concomitant	Tablets	Oral	2.5 Milligram	1 every 1 Days		Insomnia

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Lung disorder	v.24.1	
Myocardial injury	v.24.1	
Myocarditis	v.24.1	-108
Pulmonary oedema	v.24.1	
Thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04320966	0	2021-06-22	2021-06-22	MAH	2021676433	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
41 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Angina pectoris	v.24.1	15 Hours
Cardiac discomfort	v.24.1	1 Days
Dyspnoea	v.24.1	1 Days
Eating disorder	v.24.1	15 Hours
Hypoaesthesia	v.24.1	1 Days
Loss of consciousness	v.24.1	1 Days

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Movement disorder	v.24.1	15 Hours
Pain in extremity	v.24.1	2 Days
Sensory loss	v.24.1	1 Days
Speech disorder	v.24.1	15 Hours
Tremor	v.24.1	1 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04320968	1	2021-06-22	2021-07-30	MAH	2021665115	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
51 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04320983	0	2021-06-22	2021-06-22	MAH	2021677324	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
21 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ALYSENA 28	Concomitant	Tablets	Oral			886.0	Contraception
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Kidney infection	v.24.1	
Pain	v.24.1	
Painful respiration	v.24.1	
Platelet disorder	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Thrombosis	v.24.1	
Vaginal haemorrhage	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04321022	0	2021-06-22	2021-06-22	MAH	2021678004	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
34 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Haematochezia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04321025	0	2021-06-22	2021-06-22	MAH	2021666011	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
45 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
INDAYO	Concomitant	Tablets					
PANTOPRAZOLE	Concomitant	NOT SPECIFIED					
PERINDOPRIL	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
SPIRONOLACTONE	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Heavy menstrual bleeding	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:07:47 AM
Initial Received Date:	2021-06-16 to 2021-07-30
Latest Received Date:	N/A
Total Number of Reports:	802 Report(s)

Report Information

***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04321526	0	2021-06-22	2021-06-22	MAH	20210624380	Study	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown			0.0	COVID-19 prophylaxis
INFLIXIMAB	Suspect		Intravenous (not otherwise specified)	500.0 Milligram	1 every 8 Weeks		Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pneumonia legionella	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04321604	1	2021-06-22	2021-07-19	MAH	20210623124	Study	Other health professional

Serious report?
Serious

Death:	No	Disability:	No	Congenital Anomaly:	No
Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
60 Years	Male		74 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	
Linked	
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				COVID-19 prophylaxis
REMICADE	Suspect	POWDER FOR SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)				Crohn's disease
REMICADE	Suspect	Solution for infusion	Intravenous (not otherwise specified)	800.0 Milligram	1 every 4 Weeks		Crohn's disease

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pneumonia	v.24.1	2 Months
SARS-CoV-2 test positive	v.24.1	2 Months

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04321622	1	2021-06-22	2021-09-17	MAH	MOD-2021-220852	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
72 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CALCIUM CARBONATE/ERGOCALCIFEROL	Concomitant		Oral	500.0 ml			Product used for unknown indication
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Unknown	1.0 Dosage forms			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dyspnoea	v.24.1	
Hypersensitivity	v.24.1	3 Days
Muscle tightness	v.24.1	
Peripheral coldness	v.24.1	
Product dose omission issue	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Tremor	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04324460	0	2021-06-23	2021-06-23	MAH	CA202003013450	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
24 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				Immunisation
TALTZ	Suspect		Unknown	80.0 Milligram			Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arrhythmia	v.24.1	
Arthralgia	v.24.1	
Back pain	v.24.1	
Headache	v.24.1	
Myalgia	v.24.1	
Myalgia	v.24.1	
Neck pain	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pain	v.24.1	
Pain in extremity	v.24.1	
Sleep disorder	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04324803	0	2021-06-23	2021-06-23	MAH	MOD-2021-219223	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	1.0 Dosage forms			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dyskinesia	v.24.1	
Fatigue	v.24.1	
Muscle twitching	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04326145	1	2021-06-23	2021-07-21	MAH	2021606242	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
34 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Inappropriate schedule of product administration	v.24.1	
Intermenstrual bleeding	v.24.1	
Off label use	v.24.1	
Product use issue	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04326148	0	2021-06-23	2021-06-23	MAH	2021422224	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
46 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
SYNTHROID	Concomitant	NOT SPECIFIED	Oral	0.175 Milligram	1 every 1 Days		Hyperthyroidism
TRAZODONE	Concomitant		Oral	50.0 Milligram	1 every 1 Days		Insomnia
VYVANSE	Concomitant	Capsules	Oral	40.0 Milligram	1 every 1 Days		Attention deficit hyperactivity disorder
WELLBUTRIN	Concomitant	TABLET (EXTENDED-RELEASE)	Oral	300.0 Milligram	1 every 1 Days		Depression

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Erythema	v.24.1	573 Minutes
Feeling hot	v.24.1	573 Minutes
Headache	v.24.1	7 Days
Hypertension	v.24.1	
Musculoskeletal stiffness	v.24.1	7 Days
Peripheral swelling	v.24.1	573 Minutes
Swelling face	v.24.1	573 Minutes
Swelling of eyelid	v.24.1	573 Minutes
Throat tightness	v.24.1	573 Minutes

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04326161	0	2021-06-23	2021-06-23	MAH	2021676794	Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
76 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Venous thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04326265	1	2021-06-23	2021-08-03	MAH	2021716511	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
47 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Crohn's disease	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04326347	0	2021-06-23	2021-06-23	MAH	2021676559	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
43 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.24.1	
Headache	v.24.1	
Hypoaesthesia	v.24.1	
Joint dislocation	v.24.1	
Motor dysfunction	v.24.1	
Musculoskeletal discomfort	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Neck pain	v.24.1	
Pain in jaw	v.24.1	
Seizure	v.24.1	
Swollen tongue	v.24.1	
Tremor	v.24.1	
Urticaria	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04326442	2	2021-06-23	2021-09-02	MAH	2021677778	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
68 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Deafness unilateral	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04326783	1	2021-06-23	2021-08-31	MAH	21K-028-3952712-00	Study	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
45 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular			0.0	COVID-19 prophylaxis
COVID-19 VACCINE	Suspect		Intramuscular			0.0	COVID-19 prophylaxis
RISANKIZUMAB	Suspect		Subcutaneous	150.0 Milligram	1 every 12 Weeks	-6.0	Psoriasis
RISANKIZUMAB	Suspect	Solution for injection in pre-filled syringe	Subcutaneous	150.0 Milligram	1 every 8 Weeks		Psoriasis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Psoriasis	v.24.1	0

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Psoriasis	v.24.1	0
Therapeutic product effect incomplete	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04326965	1	2021-06-23	2021-08-10	MAH	2021683506	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
74 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
WARFARIN	Concomitant		Oral	2.5 Milligram	every 1 Days		Thrombosis prophylaxis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Haemorrhagic stroke	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Malaise	v.24.1	
Movement disorder	v.24.1	
Pain in extremity	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04327234	0	2021-06-23	2021-06-23	MAH	21K-028-3950884-00	Study	Consumer/other non health professional

Serious report?
Serious

Death:	No	**Disability:**	No	**Congenital Anomaly:**	No
Life Threatening:	No	**Hospitalization:**	No	**Other Medically Important Conditions:**	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
60 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular			1.0 Days	COVID-19 immunisation
HUMIRA	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous	40.0 Milligram	1 every 1 Weeks		Ankylosing spondylitis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	
Lymphadenopathy	v.24.1	
Nausea	v.24.1	
Pain in extremity	v.24.1	
Renal disorder	v.24.1	
Single functional kidney	v.24.1	
Swelling	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04328006	0	2021-06-23	2021-06-23	MAH	2021673175	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
39 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
WELLBUTRIN	Concomitant	TABLET (EXTENDED-RELEASE)					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04328058	1	2021-06-23	2021-08-20	MAH	2021529402	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
33 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Heart rate abnormal	v.24.1	
Hypotension	v.24.1	
Palpitations	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04329726	2	2021-06-24	2021-07-28	MAH	21K-028-3886486-00	Study	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
69 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular			1.0 Days	COVID-19 immunisation
HUMIRA	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous	40.0 Milligram	1 every 2 Weeks	101.0 Days	Crohn's disease

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Antibody test positive	v.24.1	
Arthritis	v.24.1	
Asthenia	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Condition aggravated	v.24.1	
Dyspnoea	v.24.1	
Headache	v.24.1	
Loss of personal independence in daily activities	v.24.1	
Malaise	v.24.1	
Malaise	v.24.1	
Psoriasis	v.24.1	
Therapeutic product effect decreased	v.24.1	
Therapeutic response shortened	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04329915	0	2021-06-24	2021-06-24	MAH	2021A557586	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Duplicate	E2B_04304896

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Immune thrombocytopenia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04330044	1	2021-06-24	2021-06-29	MAH	2021A526268	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bedridden	v.24.1	
Condition aggravated	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04330456	1	2021-06-24	2021-06-25	MAH	CA2021AMR135514	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
44 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	E2B_03101352
Linked	
Linked	
Linked	
Linked	E2B_03101352

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MEPOLIZUMAB	Suspect		Subcutaneous	100.0 Milligram			Asthma
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown				COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic shock	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04330549	1	2021-06-24	2021-07-14	MAH	CA2020AMR197102	Study	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
70 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	
Linked	
Linked	
Linked	E2B_02603968
Linked	E2B_04192636
Linked	000989784
Linked	E2B_02603968
Linked	
Linked	
Linked	E2B_04192636

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ATROVENT	Suspect	NOT SPECIFIED	Unknown	4.0 Dosage forms	1 every 1 Days		Product used for unknown indication

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ATROVENT	Suspect		Unknown				Product used for unknown indication
BUDESONIDE/FORMOTEROL FUMARATE	Suspect		Unknown				Product used for unknown indication
COVID-19 VACCINE	Suspect		Unknown				COVID-19 prophylaxis
ELIGARD	Suspect	POWDER FOR SUSPENSION, SUSTAINED-RELEASE	Unknown				Prostate cancer
MEPOLIZUMAB	Suspect	Powder for injection	Subcutaneous	100.0 Milligram			Product used for unknown indication, Asthma
MEPOLIZUMAB	Suspect		Subcutaneous	100.0 Milligram			Product used for unknown indication, Asthma
PREDNISONE	Suspect		Unknown	10.0 Milligram	1 every 1 Days		Product used for unknown indication
PREDNISONE	Suspect	NOT SPECIFIED	Unknown	10.0 Milligram	1 every 1 Days		Product used for unknown indication
PREDNISONE	Suspect		Unknown	30.0 Milligram	1 every 1 Days		Product used for unknown indication
PREDNISONE	Suspect		Unknown	50.0 Milligram	1 every 1 Days	4.0 Days	Product used for unknown indication
SPIRIVA	Suspect	NOT SPECIFIED	Unknown				Product used for unknown indication
STERILE WATER	Concomitant	LIQUID INHALATION	Unknown	1.2 ml			Vehicle solution use
VENTOLIN	Suspect		Unknown				Product used for unknown indication

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
VENTOLIN	Suspect		Unknown	4.0 Dosage forms	1 every 1 Days		Product used for unknown indication
VENTOLIN	Suspect	NOT SPECIFIED	Unknown				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cardiac failure congestive	v.24.1	
Contusion	v.24.1	
Dyspnoea	v.24.1	
Dyspnoea exertional	v.24.1	
Heart rate increased	v.24.1	
Prostate cancer	v.24.1	
Use of accessory respiratory muscles	v.24.1	
Wheezing	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04330588	1	2021-06-24	2021-07-01	MAH	CA2021AMR135390	Study	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
76 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	E2B_02352767
Linked	E2B_04335995
Linked	E2B_04335995
Linked	
Linked	
Linked	
Linked	
Linked	E2B_02854611
Linked	
Linked	E2B_02352767
Linked	E2B_01711481
Linked	
Linked	
Linked	E2B_04335995
Linked	E2B_02854611

Record Type	Link AER** Number
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	E2B_02854611
Linked	
Linked	
Linked	E2B_01711481

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Unknown				COVID-19 prophylaxis
DEXILANT	Concomitant	CAPSULE, DELAYED RELEASE	Unknown				Product used for unknown indication
IPRATROPIUM BROMIDE/SALBUTAMOL SULFATE	Concomitant		Unknown				Product used for unknown indication
MEPOLIZUMAB	Suspect		Subcutaneous	100.0 Milligram			Asthma
PULMICORT	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication
SINGULAIR	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication
SPIRIVA	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication
VENTOLIN	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Malaise	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pneumonia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04331529	0	2021-06-24	2021-06-24	MAH	2021350650	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
39 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular			1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dyspnoea	v.24.1	
Insomnia	v.24.1	
Respiratory distress	v.24.1	
Tachycardia	v.24.1	
Tachypnoea	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04331533	1	2021-06-24	2021-07-15	MAH	2021364475	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
75 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Total	1.0 Days	COVID-19 immunisation
SUTENT	Concomitant	Capsules		37.5 Milligram			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood pressure increased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04331541	0	2021-06-24	2021-06-24	MAH	2021391343	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
56 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVERSYL [PERINDOPRIL ARGININE]	Concomitant		Oral	8.0 Milligram	every 1 Days		Hypertension
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
TYLENOL	Concomitant	NOT SPECIFIED	Oral	1.0 Gram	4 every 1 Days		Arthralgia

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Axillary pain	v.24.1	
Chills	v.24.1	-94

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hot flush	v.24.1	-94
Lymphadenopathy	v.24.1	
Pain in extremity	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04331543	0	2021-06-24	2021-06-24	MAH	2021391539	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
69 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AMLODIPINE BESILATE	Concomitant		Oral	5.0 Milligram			Hypertension
CELEXA [CELECOXIB]	Concomitant		Oral	30.0 Milligram			Depression
HYDROCHLOROTHIAZIDE/ VALSARTAN	Concomitant		Oral				Hypertension
LIPITOR	Concomitant	NOT SPECIFIED	Oral	20.0 Milligram	every 1 Days		Hypercholesterolaemia
PENTASA	Concomitant	NOT SPECIFIED	Oral	3.0 Gram	every 1 Days		Colitis
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
PREDNISONE	Concomitant	NOT SPECIFIED	Oral	5.0 Milligram	every 1 Days		Colitis
PREVACID	Concomitant	NOT SPECIFIED	Oral	30.0 Milligram	every 1 Days		Dyspepsia

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest discomfort	v.24.1	
Dyspnoea	v.24.1	
Musculoskeletal stiffness	v.24.1	6 Days
Myalgia	v.24.1	6 Days
Nerve injury	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04331590	0	2021-06-24	2021-06-24	MAH	2021677256	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
20 Years	Male		69 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Back pain	v.24.1	
Crohn's disease	v.24.1	
Headache	v.24.1	
Nausea	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04331612	1	2021-06-24	2021-07-14	MAH	2021684254	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
52 Years				Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
WARFARIN	Concomitant		Oral				Thrombosis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal discomfort	v.24.1	21 Hours
Disease progression	v.24.1	
Fatigue	v.24.1	
Headache	v.24.1	21 Hours
Pain in extremity	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Purpura	v.24.1	
Systemic lupus erythematosus	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04331621	1	2021-06-24	2021-07-22	MAH	2021676375	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
33 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Paraesthesia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04331676	0	2021-06-24	2021-06-24	MAH	2021665585	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
85 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood pressure decreased	v.24.1	
Fall	v.24.1	
Head injury	v.24.1	
Loss of consciousness	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04331707	1	2021-06-24	2021-09-15	MAH	2021684287	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
58 Years	Female		65 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CITALOPRAM	Concomitant		Oral	40.0 Milligram	1 every 1 Days		
METHOTREXATE	Concomitant	NOT SPECIFIED		1.0 Dosage forms			
PANTOPRAZOLE	Concomitant	NOT SPECIFIED	Oral	40.0 Milligram	1 every 1 Days		
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation
RAMIPRIL	Concomitant	NOT SPECIFIED	Oral	7.5 Milligram	1 every 1 Days		
SYNTHROID	Concomitant	NOT SPECIFIED	Oral	125.0 Microgram	1 every 1 Days		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.24.1	
Drug ineffective	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04331758	1	2021-06-24	2021-08-06	MAH	2021676647	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
17 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ALYSENA 28	Concomitant	Tablets					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Kidney infection	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04331771	1	2021-06-24	2021-08-18	MAH	2021676298	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
24 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ETHINYL ESTRADIOL/LEVONORGESTREL	Suspect		Unknown				Contraception
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown				COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Heavy menstrual bleeding	v.24.1	
Menstruation irregular	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04331775	0	2021-06-24	2021-06-24	MAH	2021677806	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
63 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Rheumatoid arthritis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04331782	1	2021-06-24	2021-08-10	MAH	2021677130	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
41 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
SINGULAIR	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.24.1	1 Weeks
Dyspnoea	v.24.1	
Fatigue	v.24.1	1 Weeks
Fatigue	v.24.1	
Headache	v.24.1	1 Weeks

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Heart rate increased	v.24.1	
Hypertension	v.24.1	
Nausea	v.24.1	1 Weeks
Pyrexia	v.24.1	1 Weeks
Vomiting	v.24.1	1 Weeks

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04331817	1	2021-06-24	2021-09-06	MAH	2021734298	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
3 Weeks	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BUDESONIDE/FORMOTEROL FUMARATE	Concomitant		Transmammary				Asthma
NIFEDIPINE	Concomitant		Transmammary				Hypertension
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Transmammary		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Exposure via breast milk	v.24.1	
Neonatal respiratory distress	v.24.1	2 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04331826	0	2021-06-24	2021-06-24	MAH	2021677023	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ATENOLOL	Concomitant	Tablets					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown			1.0 Days	COVID-19 immunisation
STATIN [ATORVASTATIN CALCIUM]	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blindness transient	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04332099	0	2021-06-24	2021-06-24	MAH	MOD-2021-226413	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
43 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect			1.0 Dosage forms			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cellulitis	v.24.1	
Vaccination site erythema	v.24.1	
Vaccination site swelling	v.24.1	
Vaccination site warmth	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04333514	1	2021-06-24	2021-07-21	MAH	2021502346	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
50 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Months	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anxiety	v.24.1	
Burning sensation	v.24.1	
Erythema	v.24.1	
Hypersensitivity	v.24.1	
Pain	v.24.1	
Swelling face	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04334320	0	2021-06-25	2021-06-25	MAH	CANSP2021096007	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_04376396

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				Product used for unknown indication
ENBREL	Suspect		Unknown				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Seizure	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04337227	0	2021-06-25	2021-06-25	MAH	2021683243	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
45 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
TYLENOL	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Axillary pain	v.24.1	
Headache	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Vaccination site pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04337230	0	2021-06-25	2021-06-25	MAH	2021690727	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
39 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Volvulus	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04337237	1	2021-06-25	2021-07-16	MAH	2021684268	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
71 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Angina pectoris	v.24.1	
Chest pain	v.24.1	
Joint ankylosis	v.24.1	
Limb discomfort	v.24.1	
Muscular weakness	v.24.1	
Pain	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Palpitations	v.24.1	
Thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04337238	1	2021-06-25	2021-08-09	MAH	2021684182	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
23 Years	Male			Recovered/resolved with sequelae

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
OMEGA-3	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
VITAMIN C [ASCORBIC ACID]	Concomitant						
VITAMIN D	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Food allergy	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04337245	0	2021-06-25	2021-06-25	MAH	2021733264	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
47 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Months	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cerebrovascular accident	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:07:47 AM
Initial Received Date:	2021-06-16 to 2021-07-30
Latest Received Date:	N/A
Total Number of Reports:	802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04337287	0	2021-06-25	2021-06-25	MAH	2021684866	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
69 Years	Female	160 Centimeter	63 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
NOLVADEX [TAMOXIFEN]	Concomitant						Breast conserving surgery, Breast cancer
NOLVADEX [TAMOXIFEN]	Concomitant						Breast conserving surgery, Breast cancer
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthma	v.24.1	
Chills	v.24.1	
Contrast media allergy	v.24.1	
Dry mouth	v.24.1	1 Days
Dysgeusia	v.24.1	
Fatigue	v.24.1	
Gait disturbance	v.24.1	1 Days
Hypoaesthesia	v.24.1	1 Days
Malaise	v.24.1	
Nausea	v.24.1	
Pain in extremity	v.24.1	3 Days
Pruritus	v.24.1	
Rash macular	v.24.1	
Speech disorder	v.24.1	
Swollen tongue	v.24.1	1 Days
Transient ischaemic attack	v.24.1	1 Days
Urticaria	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04337289	0	2021-06-25	2021-06-25	MAH	2021684589	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
49 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Joint swelling	v.24.1	
Limb discomfort	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04337300	0	2021-06-25	2021-06-25	MAH	2021701562	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
72 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ESTROGEL METERED-DOSE PUMP	Concomitant	GEL	Topical				Menopause
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.24.1	14 Days
Circadian rhythm sleep disorder	v.24.1	
Fatigue	v.24.1	14 Days
Inappropriate affect	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Myalgia	v.24.1	14 Days
Postmenopausal haemorrhage	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04337334	0	2021-06-25	2021-06-25	MAH	2021694873	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
52 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypoaesthesia	v.24.1	
Hypoaesthesia oral	v.24.1	
Syncope	v.24.1	0 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04337376	1	2021-06-25	2021-08-04	MAH	2021691606	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
18 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CYPROTERONE;ETHINYL ESTRADIOL	Concomitant		Oral				Contraception
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Heavy menstrual bleeding	v.24.1	657 Hours
Thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04337381	0	2021-06-25	2021-06-25	MAH	2021691698	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
60 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Musculoskeletal stiffness	v.24.1	
Tremor	v.24.1	

Canada Vigilance
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Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04337383	0	2021-06-25	2021-06-25	MAH	2021691693	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
44 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain	v.24.1	
Chest pain	v.24.1	
Diarrhoea	v.24.1	
Muscle spasms	v.24.1	
Muscle twitching	v.24.1	

Canada Vigilance
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Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04337396	1	2021-06-25	2021-07-28	MAH	2021691692	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
50 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Deafness unilateral	v.24.1	
Tinnitus	v.24.1	
Tinnitus	v.24.1	
Vertigo	v.24.1	-146

Canada Vigilance
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Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04337400	1	2021-06-25	2021-08-10	MAH	2021691591	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
57 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Muscular weakness	v.24.1	
Myalgia	v.24.1	
Neuralgia	v.24.1	
Pain in extremity	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

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Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04337404	0	2021-06-25	2021-06-25	MAH	2021182317	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
27 Years	Female	168 Centimeter	75 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
D-ALPHA TOCOPHERYL ACETATE/FISH OIL/OENOTHERA BIENNIS	Concomitant				1 every 1 Days		
DICLECTIN	Concomitant	TABLET (DELAYED-RELEASE)	Oral		1 every 1 Days		Nausea
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cholelithiasis	v.24.1	
Cholestasis	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Exposure during pregnancy	v.24.1	
Vaccination site pain	v.24.1	48 Hours

Canada Vigilance
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Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04337405	3	2021-06-25	2021-09-01	MAH	2021708116	Spontaneous	Physician

Serious report?	Death:	Disability:	Congenital Anomaly:
Serious	Yes	No	No
	Life Threatening: No	**Hospitalization:** Yes	**Other Medically Important Conditions:** No

Patient Information

Age	Gender	Height	Weight	Report Outcome
102 Years	Male			Fatal

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETAMINOPHEN	Concomitant	NOT SPECIFIED			3 every 1 Days		
APIXABAN	Concomitant		Oral				
CALCIUM	Concomitant	NOT SPECIFIED		500.0 Milligram	2 every 1 Days		
COVERSYL [PERINDOPRIL ARGININE]	Concomitant	Tablet		2.0 Milligram	1 every 1 Days		
ELIQUIS FILM COATED	Concomitant	Tablets		2.5 Milligram	2 every 1 Days		
METOPROLOL	Concomitant		Oral				Atrial fibrillation
OMNARIS	Concomitant	SPRAY, METERED DOSE			1 every 1 Days		
PERINDOPRIL	Concomitant		Oral				Hypertension
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
RISEDRONATE	Concomitant	Tablets		35.0 Milligram	1 every 1 Weeks		
TIMOPTIC-XE	Concomitant	SOLUTION (LONG-ACTING)					
VITAMIN D3	Concomitant	Capsules		2000.0 IU (International Unit)	1 every 1 Days		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Balance disorder	v.24.1	
Blood pressure increased	v.24.1	
Cardiac failure congestive	v.24.1	
Confusional state	v.24.1	
Disease recurrence	v.24.1	
Fatigue	v.24.1	
Fluid retention	v.24.1	
Gait disturbance	v.24.1	
General physical health deterioration	v.24.1	
Peripheral swelling	v.24.1	
Pulmonary oedema	v.24.1	
Somnolence	v.24.1	
Weight increased	v.24.1	

Canada Vigilance
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Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04337449	0	2021-06-25	2021-06-25	MAH	2021685352	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
39 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
VORTIOXETINE HYDROBROMIDE	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest discomfort	v.24.1	
Dyspepsia	v.24.1	
Fatigue	v.24.1	
Feeling cold	v.24.1	

Canada Vigilance
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Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04337725	0	2021-06-25	2021-06-25	MAH	MOD-2021-100817	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
82 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	1.0 Dosage forms			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Erythema	v.24.1	
Headache	v.24.1	
Pain	v.24.1	
Swelling	v.24.1	
Vaccination site discomfort	v.24.1	
Vaccination site pain	v.24.1	
Vaccination site pruritus	v.24.1	2 Days

Canada Vigilance
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Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04339073	1	2021-06-25	2021-08-11	MAH	2021701448	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
45 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain	v.24.1	1 Days
Back pain	v.24.1	1 Days
Chest pain	v.24.1	0 Days
Chills	v.24.1	4 Hours
Diarrhoea	v.24.1	1 Days
Hyperhidrosis	v.24.1	4 Hours

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypoaesthesia	v.24.1	1 Days
Neck pain	v.24.1	
Pain in extremity	v.24.1	0 Days
Pain in extremity	v.24.1	1 Days
Pain in extremity	v.24.1	4 Hours
Renal pain	v.24.1	

Canada Vigilance
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Report Information ***AER = Adverse Reaction Report*

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E2B_04339093	1	2021-06-25	2021-07-27	MAH	2021690828	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
55 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ERGOCALCIFEROL	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal discomfort	v.24.1	
Abdominal distension	v.24.1	
Diarrhoea	v.24.1	
Headache	v.24.1	
Inappropriate schedule of product administration	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Muscle spasms	v.24.1	
Muscle tightness	v.24.1	
Musculoskeletal discomfort	v.24.1	
Nausea	v.24.1	
Pain in extremity	v.24.1	
Palpitations	v.24.1	
Vision blurred	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
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Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04339177	0	2021-06-25	2021-06-25	MAH	2021691064	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
58 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
VITAMIN C [ASCORBIC ACID]	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Deafness neurosensory	v.24.1	

Canada Vigilance
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Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04340733	1	2021-06-27	2021-07-12	MAH	2021702372	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
31 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.24.1	29 Hours
Pyrexia	v.24.1	29 Hours
Swelling face	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
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Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04340830	0	2021-06-27	2021-06-27	MAH	2021325506	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
72 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CANDESARTAN	Concomitant		Oral	8.0 Milligram			Blood pressure measurement
ESTRING	Concomitant	RING (SLOW-RELEASE)	Vaginal	2.0 Milligram			Hormone therapy
LIFITEGRAST	Concomitant		Intraocular		2 every 1 Days		Dry eye
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood pressure increased	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	-80
Vaccination site pain	v.24.1	

Canada Vigilance
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Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04340839	2	2021-06-27	2021-08-11	MAH	2021498639	Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
73 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BIOTIN/CALCIUM D-PANTOTHENATE/D-ALPHA TOCOPHERYL ACETATE/FOLIC ACID/NICOTINIC ACID/PYRIDOXINE HYDROCHLORIDE/RIBOFLAVIN/THIAMINE HYDROCHLORIDE/VITAMIN B12/VITAMIN C	Concomitant		Oral				Supplementation therapy
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
C-reactive protein increased	v.24.1	
Fatigue	v.24.1	8 Days
Heart rate irregular	v.24.1	8 Days
Jaw disorder	v.24.1	
Movement disorder	v.24.1	
Pain in extremity	v.24.1	1 Days
Pain in jaw	v.24.1	
Renal pain	v.24.1	5 Minutes

Canada Vigilance
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Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04340840	0	2021-06-27	2021-06-27	MAH	2021690502	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
55 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Herpes zoster	v.24.1	
Lymphadenopathy	v.24.1	
Malaise	v.24.1	
Postmenopausal haemorrhage	v.24.1	

Canada Vigilance
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Report Runtime: 2022-05-07 - 01:07:47 AM
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Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04340845	0	2021-06-27	2021-06-27	MAH	2021701172	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
79 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthropod bite	v.24.1	1 Days
Arthropod bite	v.24.1	
Arthropod bite	v.24.1	2 Days
Haemorrhage	v.24.1	
Pain in extremity	v.24.1	31 Hours

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04340848	1	2021-06-27	2021-08-09	MAH	2021691742	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
23 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal discomfort	v.24.1	
Diarrhoea	v.24.1	
Dizziness	v.24.1	
Fatigue	v.24.1	
Headache	v.24.1	
Muscle tightness	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Nausea	v.24.1	
Neck pain	v.24.1	
Pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04342274	2	2021-06-28	2021-09-23	MAH	21K-028-3757073-00	Study	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
63 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_04640104
Linked	
Linked	
Linked	E2B_04618952
Linked	
Linked	E2B_04618952
Linked	
Linked	
Linked	E2B_04640104
Linked	
Linked	
Linked	
Linked	E2B_04640104

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect	Injection	Intramuscular			0.0	COVID-19 prophylaxis
COVID-19 VACCINE	Suspect		Intramuscular			1.0 Days	COVID-19 prophylaxis
METHOTREXATE	Concomitant	NOT SPECIFIED	Oral				Product used for unknown indication
RINVOQ	Suspect	TABLET (EXTENDED-RELEASE)	Oral	15.0 Milligram	1 every 1 Days	370.0 Days	Rheumatoid arthritis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Acne	v.24.1	
Arthritis	v.24.1	
Gingival pain	v.24.1	
Inflammation	v.24.1	
Inflammation	v.24.1	
Oral mucosal exfoliation	v.24.1	
Pain in extremity	v.24.1	
Palatal disorder	v.24.1	
Skin exfoliation	v.24.1	
Therapeutic product effect decreased	v.24.1	
Ulcer	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04342543	1	2021-06-28	2021-10-18	MAH	20210634039	Study	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
26 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				Immunisation
SIMPONI I.V.	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)				Rheumatoid arthritis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.24.1	
Drug ineffective	v.24.1	
Rheumatoid arthritis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04343900	1	2021-06-28	2021-09-17	MAH	2021513194	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
81 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ATORVASTATIN	Concomitant	Tablets					
JARDIANCE	Concomitant						
METFORMIN HYDROCHLORIDE/SITAGLIPTIN PHOSPHATE MONOHYDRATE	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Vaginal haemorrhage	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04344552	0	2021-06-28	2021-06-28	MAH	2021708250	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
53 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CETIRIZINE HYDROCHLORIDE	Concomitant						Hypersensitivity
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain upper	v.24.1	
Diarrhoea	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04344580	0	2021-06-28	2021-06-28	MAH	2021702904	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
18 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BUDESONIDE/FORMOTEROL FUMARATE	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Muscle rigidity	v.24.1	
Nervous system disorder	v.24.1	
Pain	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Phlebitis	v.24.1	
Thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04344596	1	2021-06-28	2021-08-09	MAH	2021700598	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
49 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Ophthalmic herpes zoster	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04345618	2	2021-06-28	2021-07-30	MAH	20210646439	Study	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
61 Years	Male	172 Centimeter	47 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	
Linked	
Linked	
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Linked	
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	

Record Type	Link AER** Number
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				COVID-19 prophylaxis
REMICADE	Suspect	POWDER FOR SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	750.0 Milligram	1 every 6 Weeks		Colitis ulcerative

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19 pneumonia	v.24.1	29 Days
Pain	v.24.1	1 Months
Pyrexia	v.24.1	3 Months
Weight decreased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04346972	1	2021-06-29	2021-07-23	MAH	CA2021AMR137645	Study	Consumer/other non health professional

Serious report?
Serious

Death:	No	**Disability:**	No	**Congenital Anomaly:**	No
Life Threatening:	No	**Hospitalization:**	No	**Other Medically Important Conditions:**	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
79 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	E2B_05242586
Linked	E2B_05242586
Linked	E2B_04587276
Linked	E2B_04587276
Linked	E2B_03111361
Linked	
Linked	
Linked	E2B_05131515
Linked	E2B_03111361
Linked	
Linked	
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				Product used for unknown indication, COVID-19 prophylaxis
COVID-19 VACCINE	Suspect		Unknown				Product used for unknown indication, COVID-19 prophylaxis
MEPOLIZUMAB	Suspect	Powder for injection	Subcutaneous	100.0 Milligram			Product used for unknown indication, Asthma
MEPOLIZUMAB	Suspect		Subcutaneous	100.0 Milligram			Product used for unknown indication, Asthma

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Nerve compression	v.24.1	
Pneumonia	v.24.1	
Sciatica	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:07:47 AM
Initial Received Date:	2021-06-16 to 2021-07-30
Latest Received Date:	N/A
Total Number of Reports:	802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04350773	1	2021-06-29	2021-07-20	MAH	2021382790	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
62 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ATORVASTATIN	Concomitant	Tablets					
COVERSYL [PERINDOPRIL ARGININE]	Concomitant						
MYRBETRIQ	Concomitant	TABLET (EXTENDED-RELEASE)					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain upper	v.24.1	2 Days

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Blood pressure increased	v.24.1	
Cough	v.24.1	20 Days
Dysphagia	v.24.1	
Dyspnoea	v.24.1	20 Days
Fatigue	v.24.1	20 Days
Headache	v.24.1	1 Days
Lymphadenopathy	v.24.1	41 Days
Palpitations	v.24.1	20 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04350850	0	2021-06-29	2021-06-29	MAH	2021702595	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
28 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Balance disorder	v.24.1	
Muscle spasms	v.24.1	
Pain in extremity	v.24.1	
Rash	v.24.1	
Vaginal haemorrhage	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04350864	0	2021-06-29	2021-06-29	MAH	2021702389	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
59 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Atrial fibrillation	v.24.1	
Fatigue	v.24.1	
Fatigue	v.24.1	
Flushing	v.24.1	
Headache	v.24.1	
Heart rate increased	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Immobile	v.24.1	
Pain in extremity	v.24.1	
Pruritus	v.24.1	
Vaccination site erythema	v.24.1	
Vaccination site pain	v.24.1	
Vaccination site rash	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04350876	2	2021-06-29	2021-08-10	MAH	2021701820	Spontaneous	Physician

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
49 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Fatigue	v.24.1	
Headache	v.24.1	
Muscular weakness	v.24.1	
Weight increased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04350894	3	2021-06-29	2021-08-31	MAH	2021701913	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
37 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_04619301
Linked	E2B_04619301

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ETHINYL ESTRADIOL/LEVONORGESTREL	Concomitant		Oral				Contraception
NORTRIPTYLINE	Concomitant	Capsules	Oral	50.0 Milligram	1 every 1 Days		Arthralgia
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest discomfort	v.24.1	
Palpitations	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04350895	1	2021-06-29	2021-08-10	MAH	2021708586	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
56 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CANDESARTAN	Concomitant						
CHLORTHALIDONE	Concomitant	Tablets					
LIOTHYRONINE SODIUM	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
SYNTHROID	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Ovarian hyperfunction	v.24.1	
Postmenopausal haemorrhage	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04351525	0	2021-06-29	2021-06-29	MAH	MOD-2021-209493	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
89 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	1.0 Dosage forms			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cellulitis	v.24.1	
Pruritus	v.24.1	
Urticaria	v.24.1	
Vaccination site erythema	v.24.1	
Vaccination site pruritus	v.24.1	
Vaccination site rash	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Vaccination site reaction	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04351712	1	2021-06-29	2021-08-23	MAH	20210645891	Study	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
60 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				COVID-19 prophylaxis
STELARA	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous	90.0 Milligram	1 every 8 Weeks		Crohn's disease

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain	v.24.1	
Diarrhoea	v.24.1	
Frequent bowel movements	v.24.1	
General physical health deterioration	v.24.1	
Haematochezia	v.24.1	
Malaise	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04353293	0	2021-06-30	2021-06-30	MAH	2021A571499	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cardiac disorder	v.24.1	
Herpes virus infection	v.24.1	
Herpes zoster	v.24.1	
Visual impairment	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04354169	1	2021-06-30	2021-08-25	MAH	2020TUS016280	Study	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
52 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASPIRIN /00002701/	Concomitant		Unknown	81.0 Milligram	1 every 2 Days		
ASPIRIN /00002701/	Concomitant		Unknown	81.0 Milligram	1 every 1 Days		
CLINDAMYCIN	Suspect	NOT SPECIFIED	Unknown				Dental cleaning
COVID-19 VACCINE	Suspect		Unknown				COVID-19
IXAZOMIB	Suspect		Oral	4.0 Milligram			Plasma cell myeloma
IXAZOMIB	Suspect	Capsules	Oral	3.0 Milligram			Plasma cell myeloma
REVLIMID	Suspect	Capsules	Unknown	10.0 Milligram			Plasma cell myeloma

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Confusional state	v.24.1	
Diarrhoea	v.24.1	
Epistaxis	v.24.1	
Eye swelling	v.24.1	
Feeling hot	v.24.1	
Herpes zoster	v.24.1	
Myalgia	v.24.1	
Neutropenia	v.24.1	
Off label use	v.24.1	
Peripheral swelling	v.24.1	
Pyrexia	v.24.1	
Rash	v.24.1	
Rash macular	v.24.1	
Somnolence	v.24.1	
Swelling face	v.24.1	
Swelling of eyelid	v.24.1	
Thrombocytopenia	v.24.1	
Urticaria	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04355037	1	2021-06-30	2021-08-10	MAH	2021601002	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
38 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood urine present	v.24.1	
Dysuria	v.24.1	
Urinary tract infection	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04355224	0	2021-06-30	2021-06-30	MAH	2021716275	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
70 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETAMINOPHEN/CODEINE PHOSPHATE	Concomitant						
ALLOPURINOL	Concomitant						
ANDROGEL	Concomitant	GEL					
ATORVASTATIN	Concomitant						
NAPROXEN	Concomitant	NOT SPECIFIED					
PANTOPRAZOLE	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
PRAMIPEXOLE DIHYDROCHLORIDE	Concomitant						

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
SYNTHROID	Concomitant	NOT SPECIFIED					
TAMSULOSIN	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.24.1	
Diarrhoea	v.24.1	
Fatigue	v.24.1	
Myalgia	v.24.1	
Nausea	v.24.1	
Pain	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04355231	1	2021-06-30	2021-08-10	MAH	2021716381	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
38 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Body temperature fluctuation	v.24.1	
Burning sensation	v.24.1	
Neuralgia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04355248	0	2021-06-30	2021-06-30	MAH	2021716361	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
76 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CARBIDOPA/LEVODOPA	Concomitant		Oral				Parkinson's disease
DOCUSATE SODIUM	Concomitant	NOT SPECIFIED	Oral				Abnormal faeces
FESOTERODINE FUMARATE	Concomitant		Oral				
MIDODRINE	Concomitant		Oral				Hypotension
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Back pain	v.24.1	
Thrombosis	v.24.1	
Traumatic lung injury	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04355342	0	2021-06-30	2021-06-30	MAH	2021726871	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
41 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Vestibular disorder	v.24.1	
Vestibular neuronitis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04355434	1	2021-06-30	2021-08-04	MAH	2021771302	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
48 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown	0.3 ml	Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arrhythmia	v.24.1	
Heart rate increased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:07:47 AM
Initial Received Date:	2021-06-16 to 2021-07-30
Latest Received Date:	N/A
Total Number of Reports:	802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04355538	0	2021-06-30	2021-06-30	MAH	2021733498	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
34 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Back pain	v.24.1	
Feeling abnormal	v.24.1	
Limb discomfort	v.24.1	
Muscle twitching	v.24.1	-73
Pain	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Spinal cord disorder	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04355798	1	2021-06-30	2021-07-29	MAH	2021714746	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
44 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PANTOPRAZOLE	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
SYNTHROID	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Asthenia	v.24.1	
Balance disorder	v.24.1	
Bone pain	v.24.1	
Cardiac flutter	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypoaesthesia	v.24.1	
Limb discomfort	v.24.1	
Myalgia	v.24.1	
Pain in extremity	v.24.1	
Paraesthesia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04355994	1	2021-06-30	2021-08-09	MAH	2021715432	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
39 Years	Male		86 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Colitis ulcerative	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04356284	0	2021-06-30	2021-06-30	MAH	2021709671	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
77 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ARANESP	Concomitant	SOLUTION INTRAVENOUS					
CALCIUM CARBONATE	Concomitant	NOT SPECIFIED					
FAMOTIDINE	Concomitant	NOT SPECIFIED					
LANTHANUM CARBONATE HYDRATE	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
SERTRALINE HYDROCHLORIDE	Concomitant						
VITAMIN B2;VITAMIN C	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Eating disorder	v.24.1	
Fatigue	v.24.1	
Gait disturbance	v.24.1	
Haemorrhage	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Myalgia	v.24.1	
Pericardial effusion	v.24.1	
Seizure	v.24.1	
Tremor	v.24.1	
Weight decreased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04356569	0	2021-06-30	2021-06-30	MAH	2021733246	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
58 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Eye swelling	v.24.1	
Fatigue	v.24.1	
Headache	v.24.1	
Lip swelling	v.24.1	
Musculoskeletal stiffness	v.24.1	
Nasal congestion	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Paraesthesia	v.24.1	
Swelling face	v.24.1	
Swollen tongue	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04357520	0	2021-06-30	2021-06-30	MAH	20210646018	Study	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
40 Years	Female		71 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	E2B_04804465
Linked	
Linked	
Linked	E2B_04804465
Linked	E2B_04804465
Linked	E2B_04804465
Linked	E2B_04804465
Linked	E2B_04804465
Linked	E2B_04804465

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				COVID-19 prophylaxis
STELARA	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous	90.0 Milligram	1 every 8 Weeks		Crohn's disease

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain	v.24.1	
Back disorder	v.24.1	
Diarrhoea	v.24.1	
Fungal rhinitis	v.24.1	
Joint noise	v.24.1	
Malaise	v.24.1	
Myalgia	v.24.1	1 Months
Oral candidiasis	v.24.1	
Road traffic accident	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04357848	1	2021-06-30	2021-08-21	MAH	2021641528	Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
55 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_04297578
Linked	E2B_04297578
Linked	E2B_04297578
Linked	E2B_04297578
Linked	E2B_04297578
Linked	E2B_04297578

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CONSTELLA	Concomitant	Capsules	Oral		As required		Constipation
DEXILANT	Concomitant	CAPSULE, DELAYED RELEASE					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
ZOMIG	Concomitant	NOT SPECIFIED	Oral	2.5 Milligram	every 1 Days		Migraine

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood pressure fluctuation	v.24.1	
Chills	v.24.1	
Discomfort	v.24.1	
Dizziness	v.24.1	8 Days
Fatigue	v.24.1	
Headache	v.24.1	9 Days
Hypotension	v.24.1	8 Days
Inappropriate schedule of product administration	v.24.1	
Infection	v.24.1	
Lymphadenopathy	v.24.1	
Nausea	v.24.1	
Pyrexia	v.24.1	9 Days
Vaccination site pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04357871	1	2021-06-30	2021-08-16	MAH	2021714807	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
62 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Amnesia	v.24.1	
Anxiety	v.24.1	
Asthenia	v.24.1	
Disturbance in attention	v.24.1	
Insomnia	v.24.1	
Irritability	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Listless	v.24.1	
Pain in extremity	v.24.1	
Palpitations	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04357913	0	2021-06-30	2021-06-30	MAH	2021714432	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
73 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blister	v.24.1	
Neuralgia	v.24.1	
Oral mucosal blistering	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:07:47 AM
Initial Received Date:	2021-06-16 to 2021-07-30
Latest Received Date:	N/A
Total Number of Reports:	802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04358012	0	2021-06-30	2021-06-30	MAH	2021732777	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
47 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CYANOCOBALAMIN	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
VITAMIN D [COLECALCIFEROL]	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Amnesia	v.24.1	
Balance disorder	v.24.1	
Burning sensation	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dysarthria	v.24.1	
Eye pain	v.24.1	
Fatigue	v.24.1	
Gait disturbance	v.24.1	
Headache	v.24.1	
Musculoskeletal stiffness	v.24.1	
Oversensing	v.24.1	
Pain	v.24.1	
Peripheral swelling	v.24.1	
Pruritus	v.24.1	
Restlessness	v.24.1	
Somnolence	v.24.1	
Spinal pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:07:47 AM
Initial Received Date:	2021-06-16 to 2021-07-30
Latest Received Date:	N/A
Total Number of Reports:	802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04358634	0	2021-07-01	2021-07-01	MAH	CA2021AMR115172	Study	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
65 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	
Linked	E2B_01346265
Linked	
Linked	
Linked	
Linked	E2B_03185456
Linked	
Linked	E2B_02785890
Linked	E2B_02929746
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				COVID-19 prophylaxis
MEPOLIZUMAB	Suspect		Subcutaneous	100.0 Milligram			Asthma

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hospitalisation	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Product dose omission issue	v.24.1	
Tooth extraction	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04361121	1	2021-07-01	2021-08-10	MAH	2021722906	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
41 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
PROVERA	Concomitant	NOT SPECIFIED	Oral			10.0 Months	Endometrial hyperplasia

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.24.1	
Photophobia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04361300	0	2021-07-01	2021-07-01	MAH	2021726779	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
51 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Back pain	v.24.1	
Lymphadenopathy	v.24.1	
Meningitis bacterial	v.24.1	
Pain in extremity	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04361586	0	2021-07-01	2021-07-01	MAH	2021785766	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
37 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Granulomatosis with polyangiitis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04361939	0	2021-07-01	2021-07-01	MAH	2021725575	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
56 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Disturbance in attention	v.24.1	
Headache	v.24.1	
Tinnitus	v.24.1	
Vertigo	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04362301	0	2021-07-01	2021-07-01	MAH	2021734397	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	Yes
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BETA-CAROTENE/BIOTIN/CALCIUM/CHROMIUM/COPPER/FOLIC ACID/IODINE/IRON/MAGNESIUM/MANGANESE/MOLYBDENUM/NICOTINAMIDE/PANTOTHENIC ACID/PYRIDOXINE HYDROCHLORIDE/RIBOFLAVIN/SELENIUM/VITAMIN A/VITAMIN B1/VITAMIN B12/VITAMIN C/VITAMIN D/VITAMIN E/VITAMIN K1/ZINC	Concomitant						

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Transplacental		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Ascites	v.24.1	
Foetal hypokinesia	v.24.1	
Hydrops foetalis	v.24.1	
Maternal exposure during pregnancy	v.24.1	
Oedema	v.24.1	
Pleural effusion	v.24.1	
Trisomy 21	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04362310	0	2021-07-01	2021-07-01	MAH	2021710525	Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
22 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anxiety	v.24.1	
Crying	v.24.1	
Dizziness	v.24.1	
Dyskinesia	v.24.1	
Fall	v.24.1	
Head discomfort	v.24.1	
Loss of consciousness	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04362444	1	2021-07-01	2021-08-25	MAH	2021726791	Spontaneous	Physician

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
74 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETYLSALICYLIC ACID	Concomitant			81.0 Milligram	every 1 Days		
AMLODIPINE BESILATE	Concomitant		Oral	2.5 Milligram	every 1 Days		Hypertension
ATORVASTATIN CALCIUM	Concomitant	NOT SPECIFIED	Oral	80.0 Milligram	every 1 Days		Hyperlipidaemia
BACLOFEN	Concomitant	NOT SPECIFIED		5.0 Milligram	3 every 1 Days		Muscle spasms
DICLOFENAC	Concomitant		Topical	10.0 Percent	2 every 1 Days		Pain
ENOXAPARIN	Concomitant	Injection		40.0 Milligram	every 1 Days		Thrombosis prophylaxis
EZETIMIBE	Concomitant	Tablets	Oral	10.0 Milligram	every 1 Days		
HYDRALAZINE	Concomitant						
METOPROLOL	Concomitant		Oral	50.0 Milligram	2 every 1 Days		Cardiomyopathy
MIRTAZAPINE	Concomitant	Tablets	Oral	7.5 Milligram	every 1 Days		
NAPROXEN	Concomitant	NOT SPECIFIED	Oral	250.0 Milligram	2 every 1 Days		

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
RAMIPRIL	Concomitant	NOT SPECIFIED		1.0 Milligram	2 every 1 Days		Hypertension
RANITIDINE	Concomitant		Oral	150.0 Milligram	2 every 1 Days		Reflux gastritis
TRAZODONE	Concomitant		Oral	75.0 Milligram		8.0 Years	Insomnia
WARFARIN	Concomitant		Oral			22.0 Years	Cerebrovascular accident, Arteriosclerosis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Antiphospholipid syndrome	v.24.1	
Blood calcium decreased	v.24.1	
Blood phosphorus decreased	v.24.1	
Cerebral ischaemia	v.24.1	
Dysarthria	v.24.1	
Encephalomalacia	v.24.1	
Haemorrhage intracranial	v.24.1	
Haemorrhagic stroke	v.24.1	97750 Minutes
Hemiplegia	v.24.1	
Inappropriate schedule of product administration	v.24.1	
International normalised ratio decreased	v.24.1	
Lymphocyte count decreased	v.24.1	
Mitral valve incompetence	v.24.1	
Muscular weakness	v.24.1	
Pericardial haemorrhage	v.24.1	
Platelet count decreased	v.24.1	
Spine malformation	v.24.1	
Thyroid calcification	v.24.1	
Urine leukocyte esterase positive	v.24.1	
Vasogenic cerebral oedema	v.24.1	
Visual impairment	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04362605	0	2021-07-01	2021-07-01	MAH	2021733873	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
52 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
RAMIPRIL	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cerebral thrombosis	v.24.1	
Cerebrovascular accident	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:07:47 AM
Initial Received Date:	2021-06-16 to 2021-07-30
Latest Received Date:	N/A
Total Number of Reports:	802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04363312	1	2021-07-01	2021-08-09	MAH	2021745693	Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
79 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ADVAIR	Concomitant	NOT SPECIFIED					
APIXABAN	Concomitant						
AZITHROMYCIN	Concomitant	NOT SPECIFIED					
FERROUS SULFATE	Concomitant						
LEVOTHYROXINE SODIUM	Concomitant	NOT SPECIFIED					
METOPROLOL	Concomitant						
PANTOLOC [PANTOPRAZOLE]	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
SALBUTAMOL	Concomitant	NOT SPECIFIED					
TIOTROPIUM	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Body temperature increased	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Procalcitonin increased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04363330	2	2021-07-01	2021-09-02	MAH	2021727919	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
34 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Months	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.24.1	
Muscular weakness	v.24.1	
Musculoskeletal stiffness	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04363366	1	2021-07-01	2021-08-11	MAH	2021734090	Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
78 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ADVAIR	Concomitant	NOT SPECIFIED					
AZITHROMYCIN	Concomitant	NOT SPECIFIED					
ELIQUIS FILM COATED	Concomitant	Tablets					Atrial fibrillation
IRON SULPHATE	Concomitant	NOT SPECIFIED					
LEVOTHYROXINE SODIUM	Concomitant	NOT SPECIFIED					
METOPROLOL	Concomitant						
PANTOLOC [PANTOPRAZOLE]	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
SALBUTAMOL	Concomitant	NOT SPECIFIED					
TIOTROPIUM	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Acute myocardial infarction	v.24.1	
Confusional state	v.24.1	
Syncope	v.24.1	
Troponin increased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04363405	1	2021-07-01	2021-08-09	MAH	2021733482	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
60 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Months	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pancytopenia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04363770	0	2021-07-02	2021-07-02	MAH	MOD-2021-231437	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Unknown	1.0 Dosage forms			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Myocarditis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04363808	0	2021-07-02	2021-07-02	MAH	MOD-2021-231011	Spontaneous	Physician

Serious report?	Death:	Disability:	Congenital Anomaly:
Serious	No	Yes	No
	Life Threatening: No	**Hospitalization:** Yes	**Other Medically Important Conditions:** No

Patient Information

Age	Gender	Height	Weight	Report Outcome
36 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Unknown	1.0 Dosage forms			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Chills	v.24.1	
Dehydration	v.24.1	
Diarrhoea	v.24.1	
Mobility decreased	v.24.1	
Product dose omission issue	v.24.1	
Vaccination site pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04363918	1	2021-07-02	2021-07-15	MAH	MOD-2021-231323	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
67 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CALTRATE PLUS [CALCIUM;COLECALCIFEROL;COPPER;MAGNESIUM;MANGANESE;ZINC]	Concomitant		Oral	600.0 Milligram			Product used for unknown indication
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	1.0 Dosage forms			COVID-19 immunisation
KRILL OIL	Concomitant	Capsule	Oral	1500.0 Milligram			Product used for unknown indication
TOZINAMERAN	Suspect		Unknown	1.0 Dosage forms			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Intentional dose omission	v.24.1	1 Days
Vitreous detachment	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04366477	0	2021-07-02	2021-07-02	MAH	2021727981	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
41 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BIPHENTIN	Concomitant	CAPSULE, EXTENDED RELEASE		50.0 Milligram			Attention deficit hyperactivity disorder
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Back pain	v.24.1	
Dysmenorrhoea	v.24.1	
Heavy menstrual bleeding	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:07:47 AM
Initial Received Date:	2021-06-16 to 2021-07-30
Latest Received Date:	N/A
Total Number of Reports:	802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04366611	1	2021-07-02	2021-08-20	MAH	2021746226	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
70 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CIPRALEX [ESCITALOPRAM]	Concomitant		Oral				Depression
PERINDOPRIL ARGININE	Concomitant		Oral				Blood cholesterol increased
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
RAMIPRIL	Concomitant	NOT SPECIFIED	Oral				Hypertension
VARICELLA ZOSTER VACCINE LIVE	Suspect		Unknown			1.0 Days	Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cellulitis	v.24.1	
Herpes zoster	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04366773	0	2021-07-02	2021-07-02	MAH	2021734392	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
70 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ATORVASTATIN	Concomitant						
BORAGO OFFICINALIS/FISH OIL/LINUM USITATISSIMUM	Concomitant						
CALCIUM	Concomitant	NOT SPECIFIED					
HYDROCHLOROTHIAZIDE	Concomitant	Tablets					
MAGNESIUM	Concomitant	NOT SPECIFIED					
MINERALS NOS/VITAMINS NOS	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
TELMISARTAN	Concomitant	Tablets					

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
VITAMIN D3	Concomitant	Capsules					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bell's palsy	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04366798	1	2021-07-02	2021-07-19	MAH	2021746661	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
67 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Deafness	v.24.1	29 Hours
Inappropriate schedule of product administration	v.24.1	
Off label use	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04367171	0	2021-07-02	2021-07-02	MAH	2021558745	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
22 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown			1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Burning sensation	v.24.1	
Urinary tract infection	v.24.1	
Urine abnormality	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04367331	0	2021-07-02	2021-07-02	MAH	2021746718	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
67 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Deafness unilateral	v.24.1	
Ear pain	v.24.1	
Hypoaesthesia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04367378	0	2021-07-02	2021-07-02	MAH	2021737240	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
31 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown			1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.24.1	
Angioedema	v.24.1	
Hypoaesthesia	v.24.1	
Paraesthesia oral	v.24.1	
Speech disorder	v.24.1	
Swollen tongue	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04368424	0	2021-07-02	2021-07-02	MAH	2021733826	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
69 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
HYDROCHLOROTHIAZIDE/ OLMESARTAN MEDOXOMIL	Concomitant		Oral				Blood pressure measurement
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Balance disorder	v.24.1	
Diarrhoea	v.24.1	
Hyperhidrosis	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Loss of consciousness	v.24.1	
Nausea	v.24.1	
Visual field defect	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04368813	2	2021-07-02	2021-07-14	MAH	MOD-2021-230943	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
55 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	1.0 Dosage forms			COVID-19 immunisation
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	Injection	Intramuscular	1.0 Dosage forms			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cardiac arrest	v.24.1	
Inappropriate schedule of product administration	v.24.1	1 Days

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Myocarditis	v.24.1	
Pyrexia	v.24.1	
Vaccination complication	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:07:47 AM
Initial Received Date:	2021-06-16 to 2021-07-30
Latest Received Date:	N/A
Total Number of Reports:	802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04369180	1	2021-07-02	2021-08-09	MAH	2021733965	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
63 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CHADOX1 NCOV-19	Suspect		Unknown			1.0 Days	COVID-19 immunisation
ELTROXIN	Concomitant	Tablets					Hypothyroidism
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
WILD YAM [DIOSCOREA VILLOSA]	Concomitant			400.0 Milligram			
ZOPICLONE	Concomitant	Tablets		7.5 Milligram			Insomnia

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest discomfort	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.24.1	
Confusional state	v.24.1	
Cough	v.24.1	
Decreased appetite	v.24.1	
Dizziness	v.24.1	
Fatigue	v.24.1	
Headache	v.24.1	3 Days
Interchange of vaccine products	v.24.1	
Nausea	v.24.1	2 Days
Off label use	v.24.1	
Pain	v.24.1	
Pyrexia	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04369184	0	2021-07-02	2021-07-02	MAH	2021734153	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
31 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
VENLAFAXINE	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain upper	v.24.1	
Arthralgia	v.24.1	
Diarrhoea	v.24.1	
Fatigue	v.24.1	
Migraine	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pain	v.24.1	
Peripheral swelling	v.24.1	
Pyrexia	v.24.1	
Rash	v.24.1	
Thinking abnormal	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04369237	1	2021-07-02	2021-08-18	MAH	2021735024	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
PREDNISONE ACETATE	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anal incontinence	v.24.1	
Arthralgia	v.24.1	
Asthenia	v.24.1	
Chest pain	v.24.1	
Cognitive disorder	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dysphagia	v.24.1	
Fatigue	v.24.1	
Heart rate increased	v.24.1	
Incontinence	v.24.1	
Muscle spasms	v.24.1	
Myalgia	v.24.1	
Neuralgia	v.24.1	
Peripheral swelling	v.24.1	
Speech disorder	v.24.1	
Syncope	v.24.1	
Vertigo	v.24.1	
Walking disability	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04370197	0	2021-07-02	2021-07-02	MAH	2021654625	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
54 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anti-cyclic citrullinated peptide antibody positive	v.24.1	
Arthralgia	v.24.1	
Back pain	v.24.1	
Fatigue	v.24.1	
Gait disturbance	v.24.1	
Insomnia	v.24.1	2 Days
Nausea	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Osteoarthritis	v.24.1	
Pain in extremity	v.24.1	
Rheumatoid factor increased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:07:47 AM
Initial Received Date:	2021-06-16 to 2021-07-30
Latest Received Date:	N/A
Total Number of Reports:	802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04370202	0	2021-07-02	2021-07-02	MAH	2021735092	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
48 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Inappropriate schedule of product administration	v.24.1	
Swelling	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04370431	0	2021-07-02	2021-07-02	MAH	2021745326	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
31 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COBALTOUS SULFATE/COPPER SULFATE/CYANOCOBALAMIN/D-ALPHA TOCOPHEROL/ERGOCALCIFEROL/FERROUS FUMARATE/MAGNESIUM SULFATE/MANGANESE SULFATE/NICOTINAMIDE/POTASSIUM IODIDE/PYRIDOXINE HYDROCHLORIDE/RIBOFLAVIN/THIAMINE HYDROCHLORIDE/VITAMIN A/VITAMIN C	Concomitant						

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cardiac disorder	v.24.1	
Chest discomfort	v.24.1	
Chest pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04371646	1	2021-07-04	2021-08-18	MAH	2021738248	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
52 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CITALOPRAM	Concomitant						
LEVOTHYROXINE SODIUM	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
RAMIPRIL	Concomitant	NOT SPECIFIED					
TYLENOL	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Inappropriate schedule of product administration	v.24.1	
Lymphadenopathy	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04375368	1	2021-07-05	2021-07-22	MAH	2021747723	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
17 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CLOBAZAM	Concomitant						
CLOBAZAM	Concomitant	Tablets					Epilepsy
CYPROHEPTADINE HYDROCHLORIDE	Concomitant						Appetite disorder
LAMICTAL	Concomitant	Tablets					Epilepsy
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
TOPAMAX	Concomitant	NOT SPECIFIED					Epilepsy

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Generalised tonic-clonic seizure	v.24.1	2 Minutes
Inappropriate schedule of product administration	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04375808	0	2021-07-05	2021-07-05	MAH	2021684222	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
61 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BLEXTEN	Concomitant	Tablets			2 every 1 Days		
BUDESONIDE/FORMOTEROL FUMARATE	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
TERBUTALINE SULFATE	Concomitant						
ZANTAC	Concomitant	NOT SPECIFIED			2 every 1 Days		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Cough	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.24.1	
Dysphonia	v.24.1	
Erythema	v.24.1	
Feeling hot	v.24.1	
Flushing	v.24.1	
Hypoaesthesia oral	v.24.1	
Lip swelling	v.24.1	
Oropharyngeal discomfort	v.24.1	
Palpitations	v.24.1	
Pharyngeal swelling	v.24.1	
Rash macular	v.24.1	
Throat tightness	v.24.1	
Urticaria	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04376191	1	2021-07-05	2021-08-18	MAH	2021738417	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
49 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
OMEGA 3-6-9	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
VITAMIN D	Concomitant						
VITAMIN K NOS	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Back pain	v.24.1	
Brain oedema	v.24.1	
Crying	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Electric shock sensation	v.24.1	
Emotional disorder	v.24.1	
Fatigue	v.24.1	
Feeling drunk	v.24.1	
Headache	v.24.1	
Hypoaesthesia	v.24.1	
Hypokinesia	v.24.1	
Muscular weakness	v.24.1	
Nightmare	v.24.1	
Paraesthesia	v.24.1	
Pyrexia	v.24.1	
Slow speech	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:07:47 AM
Initial Received Date:	2021-06-16 to 2021-07-30
Latest Received Date:	N/A
Total Number of Reports:	802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04376250	1	2021-07-05	2021-08-03	MAH	2021739366	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
40 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
PREDNISONE	Concomitant	NOT SPECIFIED	Oral	30.0 Milligram		4.0 Months	Sarcoidosis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04376396	0	2021-07-05	2021-07-05	MAH	2021775532	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Duplicate	E2B_04334320

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ENBREL	Suspect		Unknown				Product used for unknown indication
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	0.0	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Seizure	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04376464	0	2021-07-05	2021-07-05	MAH	2021747297	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
37 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
SYNTHROID	Concomitant	NOT SPECIFIED					
VENTOLIN ACCUHALER	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypokinesia	v.24.1	
Pain in extremity	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04376554	0	2021-07-05	2021-07-05	MAH	2021690652	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
61 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ECHINACEA	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
VITAMIN D [COLECALCIFEROL]	Concomitant						
ZINC	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Decreased appetite	v.24.1	
Dysstasia	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Erythema	v.24.1	
Head discomfort	v.24.1	
Joint swelling	v.24.1	
Nausea	v.24.1	
Ocular discomfort	v.24.1	
Pain in extremity	v.24.1	
Pyrexia	v.24.1	0 Months

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04376562	1	2021-07-05	2021-08-09	MAH	2021690854	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
30 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
SERTRALINE HYDROCHLORIDE	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Pain in extremity	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04376646	0	2021-07-05	2021-07-05	MAH	2021754360	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
58 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CHADOX1 NCOV-19	Suspect		Intramuscular			1.0 Days	COVID-19 immunisation
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular			1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Feeling hot	v.24.1	
Hallucination	v.24.1	
Headache	v.24.1	1 Days
Hyperhidrosis	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypotonia	v.24.1	
Pain	v.24.1	
Product use issue	v.24.1	
Pyrexia	v.24.1	1 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04376717	1	2021-07-05	2021-08-04	MAH	2021752348	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
40 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
PREDNISONE	Concomitant	NOT SPECIFIED		30.0 Milligram			Sarcoidosis
URSODIOL	Concomitant		Oral				Liver injury

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Gait inability	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Joint dislocation	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Ligament rupture	v.24.1	
Off label use	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04376754	1	2021-07-05	2021-08-05	MAH	2021747470	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
44 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETAMINOPHEN	Concomitant						
BUDESONIDE/FORMOTEROL FUMARATE	Concomitant				As required		Asthma
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
VENTOLIN [SALBUTAMOL SULFATE]	Concomitant				As required		Asthma

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaemia	v.24.1	-142
Haemoglobin decreased	v.24.1	-142
Heavy menstrual bleeding	v.24.1	-142

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Menstruation irregular	v.24.1	-142

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04377009	0	2021-07-05	2021-07-05	MAH	MOD-2021-237306	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
39 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	1.0 Dosage forms			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Atrial fibrillation	v.24.1	
Dizziness	v.24.1	
Dyspnoea	v.24.1	
Fall	v.24.1	
Feeling cold	v.24.1	
Hypoaesthesia	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Loss of consciousness	v.24.1	
Loss of personal independence in daily activities	v.24.1	
Mobility decreased	v.24.1	
Muscle spasms	v.24.1	
Paraesthesia	v.24.1	
Paralysis	v.24.1	
Respiratory rate increased	v.24.1	
Seizure	v.24.1	
Vaccination complication	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04377099	1	2021-07-05	2021-08-25	MAH	2021749262	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
22 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
DESOGESTREL/ETHINYL ESTRADIOL	Concomitant		Oral				Oral contraception
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Carditis	v.24.1	
Chest pain	v.24.1	612 Hours
Dyspnoea	v.24.1	
Headache	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypoaesthesia	v.24.1	
Myalgia	v.24.1	
Nausea	v.24.1	
Palpitations	v.24.1	16 Days
Paraesthesia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04378316	0	2021-07-06	2021-07-06	MAH	MOD-2021-237242	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
38 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	1.0 Dosage forms			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain upper	v.24.1	
Blindness transient	v.24.1	
Chills	v.24.1	
Diarrhoea	v.24.1	
Dizziness	v.24.1	
Fatigue	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.24.1	
Heavy menstrual bleeding	v.24.1	
Myalgia	v.24.1	
Rash	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04379452	0	2021-07-06	2021-07-06	MAH	2021-PMS-01165	Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown			1.0 Days	Product used for unknown indication
PMS-RAMIPRIL-HCTZ	Suspect	Tablets	Unknown				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Allergic reaction to excipient	v.24.1	
Hypersensitivity	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:07:47 AM
Initial Received Date:	2021-06-16 to 2021-07-30
Latest Received Date:	N/A
Total Number of Reports:	802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04381739	1	2021-07-06	2021-08-26	MAH	2021765729	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
78 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BRIVLERA	Concomitant	SOLUTION ORAL	Oral				Epilepsy
CYANOCOBALAMIN	Concomitant		Oral				
DOCUSATE CALCIUM	Concomitant	Capsules	Oral				Laxative supportive care
ERGOCALCIFEROL	Concomitant		Oral	2000.0 Milligram	every 1 Days		
FYCOMPA	Concomitant		Oral				Epilepsy
MAGNESIUM	Concomitant	NOT SPECIFIED	Oral				
METOPROLOL	Concomitant		Oral				Hypertension
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
RABEPRAZOLE	Concomitant		Oral				Dyspepsia
SENOKOT	Concomitant	Tablet	Oral				Laxative supportive care
XARELTO	Concomitant	Coated tablet	Oral				Atrial fibrillation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal discomfort	v.24.1	-80
Dyskinesia	v.24.1	
Movement disorder	v.24.1	
Nausea	v.24.1	-80
Neuropathy peripheral	v.24.1	
Vomiting	v.24.1	-80

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04381812	1	2021-07-06	2021-08-13	MAH	2021756585	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
65 Years	Female			Recovered/resolved with sequelae

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.24.1	
Fatigue	v.24.1	
Nausea	v.24.1	
Pain	v.24.1	
Pyrexia	v.24.1	
Vertigo	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04381906	0	2021-07-06	2021-07-06	MAH	2021756362	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
43 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CYCLOBENZAPRINE	Concomitant		Unknown				
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
TRAZODONE HYDROCHLORIDE	Concomitant			50.0 Milligram			
VITAMINS NOS	Concomitant		Unknown				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Breast haemorrhage	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04381938	1	2021-07-06	2021-08-25	MAH	2021753451	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
37 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
VITAMIN C [ASCORBIC ACID]	Concomitant						
VITAMIN D	Concomitant						
ZINC	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Diplopia	v.24.1	4 Hours
Dizziness	v.24.1	1 Months
Flushing	v.24.1	1 Hours

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Gait inability	v.24.1	1 Months
Nausea	v.24.1	1 Months
Rash erythematous	v.24.1	7 Days
Rash pruritic	v.24.1	7 Days
Urticaria	v.24.1	
Vertigo	v.24.1	1 Months
Vomiting	v.24.1	1 Months

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:07:47 AM
Initial Received Date:	2021-06-16 to 2021-07-30
Latest Received Date:	N/A
Total Number of Reports:	802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04382237	0	2021-07-06	2021-07-06	MAH	2021749277	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bell's palsy	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04382284	1	2021-07-06	2021-08-23	MAH	2021764353	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
15 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anxiety	v.24.1	
Blood pressure diastolic increased	v.24.1	
Headache	v.24.1	
Heart rate increased	v.24.1	
Nausea	v.24.1	
Syncope	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04382367	1	2021-07-06	2021-09-17	MAH	2021753426	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
20 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
DESOGESTREL/ETHINYL ESTRADIOL	Concomitant		Oral				Contraception
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bell's palsy	v.24.1	
Eye pain	v.24.1	
Herpes virus infection	v.24.1	
Pain in extremity	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04382737	0	2021-07-06	2021-07-06	MAH	2021755612	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
26 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	1 Days
Dyspnoea	v.24.1	1 Days
Fall	v.24.1	
Fatigue	v.24.1	1 Days
Haematoma	v.24.1	
Headache	v.24.1	1 Days

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pain in extremity	v.24.1	1 Days
Skin laceration	v.24.1	
Syncope	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04382809	2	2021-07-06	2021-08-11	MAH	2021735672	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
75 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	
Hypersomnia	v.24.1	
Lethargy	v.24.1	
Mobility decreased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04382843	0	2021-07-06	2021-07-06	MAH	2021745482	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
22 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MOMETASONE [MOMETASONE FUROATE]	Concomitant	Nasal spray	Intra-nasal				
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
SACCHARATED IRON OXIDE	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Back pain	v.24.1	
Chest discomfort	v.24.1	
Dizziness	v.24.1	
Dyspnoea	v.24.1	
Heart rate increased	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Insomnia	v.24.1	
Muscle twitching	v.24.1	
Palpitations	v.24.1	
Tachycardia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04382851	1	2021-07-06	2021-09-06	MAH	2021748224	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
76 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cardiac disorder	v.24.1	
Dyspnoea	v.24.1	
Heart rate decreased	v.24.1	
Palpitations	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04382853	0	2021-07-06	2021-07-06	MAH	2021764060	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
47 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
SYNTHROID	Concomitant	NOT SPECIFIED					
WELLBUTRIN	Concomitant	TABLET (EXTENDED-RELEASE)					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Inappropriate schedule of product administration	v.24.1	
Muscular weakness	v.24.1	
Syncope	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Vertigo	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:07:47 AM
Initial Received Date:	2021-06-16 to 2021-07-30
Latest Received Date:	N/A
Total Number of Reports:	802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04382871	2	2021-07-06	2021-08-20	MAH	2021756351	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
16 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ETHINYL ESTRADIOL/LEVONORGESTREL	Concomitant		Oral				Oral contraception
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Heavy menstrual bleeding	v.24.1	
Intermenstrual bleeding	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04382876	1	2021-07-06	2021-09-06	MAH	2021747999	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
61 Years				Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Condition aggravated	v.24.1	
Loss of personal independence in daily activities	v.24.1	
Muscle atrophy	v.24.1	
Muscular weakness	v.24.1	
Sensory disturbance	v.24.1	
Spinal column injury	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Spinal shock	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04384252	1	2021-07-07	2021-07-14	MAH	CA2021AMR143355	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
73 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	E2B_04535839
Linked	
Linked	
Linked	
Linked	
Linked	E2B_04535839
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				COVID-19 prophylaxis

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MEPOLIZUMAB	Suspect		Subcutaneous	100.0 Milligram			Asthma

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arterial angioplasty	v.24.1	
Cough	v.24.1	
Dyspnoea	v.24.1	
Fatigue	v.24.1	
Hospitalisation	v.24.1	
Inappropriate schedule of product administration	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04384633	1	2021-07-07	2021-08-13	MAH	CA2021AMR147229	Study	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
73 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_02548529
Linked	
Linked	
Linked	E2B_02548529
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				COVID-19 prophylaxis
MEPOLIZUMAB	Suspect		Subcutaneous	100.0 Milligram			Asthma

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypoglycaemia	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Pneumonia	v.24.1	
Product dose omission issue	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04384716	3	2021-07-07	2021-11-24	MAH	EU-2021-00996	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
78 Years	Female	159 Centimeter	62 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect						Product used for unknown indication
LONSURF	Suspect	Tablets	Oral	40.0 Milligram	1 every .5 Days		Colorectal cancer metastatic
LONSURF	Suspect	Tablets	Oral	45.0 Milligram	1 every .5 Days		Colorectal cancer metastatic
LONSURF	Suspect	Tablets	Oral	55.0 Milligram	1 every .5 Days		Colorectal cancer metastatic

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Alopecia	v.24.1	
Asthenia	v.24.1	
Dyspepsia	v.24.1	
Fatigue	v.24.1	
Full blood count abnormal	v.24.1	
Muscular weakness	v.24.1	
Musculoskeletal discomfort	v.24.1	
Nausea	v.24.1	
Onychoclasis	v.24.1	
Red blood cell count decreased	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04384742	0	2021-07-07	2021-07-07	MAH	21K-028-3970862-00	Study	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
65 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular			1.0 Days	COVID-19 prophylaxis
RINVOQ	Suspect	Prolonged-release tablet	Oral	15.0 Milligram	1 every 1 Days	155.0	Rheumatoid arthritis
RINVOQ	Suspect	TABLET (EXTENDED-RELEASE)	Oral	15.0 Milligram	1 every 1 Days	9.0 Months	Rheumatoid arthritis
RINVOQ	Suspect	Prolonged-release tablet	Oral	15.0 Milligram	1 every 1 Days		Rheumatoid arthritis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bacteraemia	v.24.1	1 Months
Endodontic procedure	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypoaesthesia	v.24.1	
Hypoaesthesia oral	v.24.1	
Joint dislocation	v.24.1	
Joint noise	v.24.1	
Malaise	v.24.1	
Pain	v.24.1	
Pain in jaw	v.24.1	
Post procedural complication	v.24.1	
Retching	v.24.1	
Rheumatoid arthritis	v.24.1	
Vomiting	v.24.1	
White blood cell count abnormal	v.24.1	
Wisdom teeth removal	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04385676	1	2021-07-07	2021-08-20	MAH	2021748272	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
56 Years	Male	183 Centimeter	88 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AMLODIPINE + ATORVASTATIN	Concomitant						Blood pressure measurement, Blood cholesterol
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
VOLTAREN [DICLOFENAC]	Concomitant						Arthritis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Limb discomfort	v.24.1	
Malaise	v.24.1	
Movement disorder	v.24.1	
Somnolence	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04385883	0	2021-07-07	2021-07-07	MAH	2021805580	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
28 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CYANOCOBALAMIN	Concomitant						
ETHINYL ESTRADIOL/LEVONORGESTREL	Concomitant						Contraception
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown	0.3 ml	Total	1.0 Days	COVID-19 immunisation
VITAMIN D	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	
Gait disturbance	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Loss of personal independence in daily activities	v.24.1	
Sensitive skin	v.24.1	1 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:07:47 AM
Initial Received Date:	2021-06-16 to 2021-07-30
Latest Received Date:	N/A
Total Number of Reports:	802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04385886	1	2021-07-07	2021-07-13	MAH	2021765730	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
78 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BRIVLERA	Concomitant	SOLUTION ORAL	Oral				Epilepsy
FYCOMPA	Concomitant		Oral				Epilepsy
MAGNESIUM	Concomitant	NOT SPECIFIED	Oral				
METOPROLOL	Concomitant		Oral				Blood pressure abnormal
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
RABEPRAZOLE	Concomitant		Oral				Dyspepsia
SENOKOT	Concomitant	Tablet	Oral				Faeces soft
VITAMIN D3	Concomitant		Oral	2000.0 Milligram			

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
VITAMINE B12	Concomitant		Oral				
XARELTO	Concomitant	Coated tablet	Oral				Atrial fibrillation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Condition aggravated	v.24.1	
Dyskinesia	v.24.1	
Epilepsy	v.24.1	
Inappropriate schedule of product administration	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04386024	1	2021-07-07	2021-08-13	MAH	2021766529	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
45 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cerebrovascular accident	v.24.1	
Deafness neurosensory	v.24.1	
Ear pain	v.24.1	8 Hours
Hypoacusis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04386383	0	2021-07-07	2021-07-07	MAH	2021765886	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
52 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood pressure increased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04387036	1	2021-07-07	2021-07-14	MAH	2021766665	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
26 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
VENLAFAXINE HYDROCHLORIDE	Concomitant			300.0 Milligram			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.24.1	
Cough	v.24.1	
Dizziness	v.24.1	
Fatigue	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Inappropriate schedule of product administration	v.24.1	
Loss of consciousness	v.24.1	
Pain	v.24.1	
Painful respiration	v.24.1	
Syncope	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04387150	0	2021-07-07	2021-07-07	MAH	2021766738	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
84 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	10 Days
Balance disorder	v.24.1	10 Days
Bradycardia	v.24.1	
Chills	v.24.1	10 Days
Dizziness	v.24.1	10 Days
Dyspnoea	v.24.1	
Fatigue	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Gait disturbance	v.24.1	10 Days
Headache	v.24.1	10 Days
Musculoskeletal stiffness	v.24.1	10 Days
Nausea	v.24.1	10 Days
Rhinorrhoea	v.24.1	10 Days
Vomiting	v.24.1	10 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04387226	0	2021-07-07	2021-07-07	MAH	2021773454	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
58 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_04617795

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest discomfort	v.24.1	
Chills	v.24.1	
Dyspnoea	v.24.1	
Headache	v.24.1	
Hyperhidrosis	v.24.1	
Myalgia	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Myocardial infarction	v.24.1	
Pericarditis	v.24.1	
Pyrexia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04387520	1	2021-07-07	2021-08-01	MAH	2021A597751	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
43 Years	Female	173 Centimeter	114 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.5 ml		1.0 Days	COVID-19 immunisation
VYVANSE	Concomitant	Capsules	Unknown				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Heavy menstrual bleeding	v.24.1	
Menstruation irregular	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04388689	1	2021-07-07	2021-08-24	MAH	2021771260	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
78 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
ROSUVASTATIN	Concomitant	NOT SPECIFIED	Oral	1.0 Dosage forms	every 1 Days		Blood cholesterol increased

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.24.1	
Inappropriate schedule of product administration	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04388735	1	2021-07-07	2021-08-23	MAH	2021757410	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
26 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MIRENA	Concomitant	INSERT (EXTENDED-RELEASE)	Intra-uterine				Contraception
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
SERTRALINE	Concomitant	Capsules		125.0 Milligram			Obsessive-compulsive disorder

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Vertigo	v.24.1	5 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:07:47 AM
Initial Received Date:	2021-06-16 to 2021-07-30
Latest Received Date:	N/A
Total Number of Reports:	802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04389160	0	2021-07-07	2021-07-07	MAH	2021766268	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
52 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthritis	v.24.1	
Gait inability	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04390247	0	2021-07-08	2021-07-08	MAH	2021A600787	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
62 Years	Male	180 Centimeter	108 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dyspnoea	v.24.1	3 Months
Impaired work ability	v.24.1	
Mental disorder	v.24.1	
Muscle enzyme increased	v.24.1	3 Months
Myalgia	v.24.1	3 Months
Sleep disorder	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04392328	0	2021-07-08	2021-07-08	MAH	MOD-2021-240768	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
73 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	1.0 Dosage forms			COVID-19 immunisation
TOZINAMERAN	Suspect		Unknown	1.0 Dosage forms			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cellulitis	v.24.1	
Chest discomfort	v.24.1	
Dizziness	v.24.1	
Interchange of vaccine products	v.24.1	
Oropharyngeal pain	v.24.1	24 Hours

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pain in extremity	v.24.1	
Rash erythematous	v.24.1	
Skin warm	v.24.1	
Vaccination site erythema	v.24.1	
Vaccination site swelling	v.24.1	
Vaccination site warmth	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04392329	0	2021-07-08	2021-07-08	MAH	20210667757	Study	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
51 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown			1.0 Days	COVID-19 prophylaxis
STELARA	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous				Crohn's disease

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Lower respiratory tract infection	v.24.1	
Pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04393091	0	2021-07-08	2021-07-08	MAH	2021A589067	Published	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
61 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASPIRIN	Concomitant	NOT SPECIFIED					
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Product used for unknown indication
BISOPROLOL	Concomitant						
CLOPIDOGREL	Concomitant	Tablets					
DALTEPARIN SODIUM	Concomitant						
NABILONE	Concomitant	NOT SPECIFIED					
PANTOPRAZOLE	Concomitant	NOT SPECIFIED					
ROSUVASTATIN CALCIUM	Concomitant						
TELMISARTAN	Concomitant	Tablets					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Back pain	v.24.1	
Deep vein thrombosis	v.24.1	
Dyspnoea	v.24.1	
Haemoptysis	v.24.1	
Immune thrombocytopenia	v.24.1	
Presyncope	v.24.1	
Pulmonary embolism	v.24.1	
Thrombocytopenia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04393827	0	2021-07-08	2021-07-08	MAH	2021783456	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
36 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
METHYLCOBALAMIN	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
VITAMIN D3	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain	v.24.1	
Ovarian cyst ruptured	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:07:47 AM
Initial Received Date:	2021-06-16 to 2021-07-30
Latest Received Date:	N/A
Total Number of Reports:	802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04393973	1	2021-07-08	2021-08-04	MAH	2021633711	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
35 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BREO ELLIPTA	Concomitant	INHALATION			every 1 Days		Asthma
CENTRUM	Concomitant	Tablets		2.0 Dosage forms	every 1 Days		
CLARITIN [LORATADINE]	Concomitant		Oral				Seasonal allergy, Dust allergy
CLARITIN [LORATADINE]	Concomitant		Oral				Seasonal allergy, Dust allergy
DESOGESTREL/ETHINYL ESTRADIOL	Concomitant		Oral	1.0 Dosage forms	every 1 Days		Contraception

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cerebral disorder	v.24.1	27 Days
Ecchymosis	v.24.1	27 Days
Eye pain	v.24.1	27 Days
Fatigue	v.24.1	27 Days
Muscle twitching	v.24.1	1 Months
Pain in extremity	v.24.1	39 Hours
Pain in extremity	v.24.1	27 Days
Palpitations	v.24.1	1 Months
Paraesthesia	v.24.1	27 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04394173	1	2021-07-08	2021-08-23	MAH	2021785251	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
82 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cerebrovascular accident	v.24.1	
Seizure	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04394681	1	2021-07-08	2021-08-16	MAH	2021774717	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
49 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bell's palsy	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04395142	2	2021-07-08	2021-09-08	MAH	2021775202	Spontaneous	Physician

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
68 Years	Male			Recovered/resolved with sequelae

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bell's palsy	v.24.1	
Head injury	v.24.1	
Headache	v.24.1	
IIIrd nerve paralysis	v.24.1	
Intracranial aneurysm	v.24.1	
Mydriasis	v.24.1	
Ocular discomfort	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Somnolence	v.24.1	
Subarachnoid haemorrhage	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04395259	2	2021-07-08	2021-09-16	MAH	2021773557	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
69 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bipolar disorder	v.24.1	
Poor quality sleep	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04395280	1	2021-07-08	2021-07-13	MAH	2021766748	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
15 Years	Male			Recovered/resolved with sequelae

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Eye swelling	v.24.1	0 Months

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:07:47 AM
Initial Received Date:	2021-06-16 to 2021-07-30
Latest Received Date:	N/A
Total Number of Reports:	802 Report(s)

Report Information

***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04395307	1	2021-07-08	2021-07-20	MAH	2021773366	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
44 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Heavy menstrual bleeding	v.24.1	
Menstruation irregular	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04395338	1	2021-07-08	2021-08-13	MAH	2021772184	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
55 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Gait inability	v.24.1	
Muscle disorder	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04395466	0	2021-07-08	2021-07-08	MAH	2021782397	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
27 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
FOLIC ACID	Concomitant	NOT SPECIFIED		1.0 Milligram			
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abortion spontaneous	v.24.1	
Vaginal haemorrhage	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04395474	1	2021-07-08	2021-08-13	MAH	2021774776	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
47 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
WELLBUTRIN	Concomitant	TABLET (EXTENDED-RELEASE)					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dysmenorrhoea	v.24.1	
Postmenopausal haemorrhage	v.24.1	
Pyrexia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04396258	0	2021-07-09	2021-07-09	MAH	MOD-2021-245530	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Unknown	1.0 Dosage forms			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:07:47 AM
Initial Received Date:	2021-06-16 to 2021-07-30
Latest Received Date:	N/A
Total Number of Reports:	802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04399321	1	2021-07-09	2021-09-01	MAH	A202107576	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				COVID-19 immunisation
SOLIRIS SINGLE USE, 300 MG/30ML	Suspect	SOLUTION INTRAVENOUS	Unknown				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hospitalisation	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:07:47 AM
Initial Received Date:	2021-06-16 to 2021-07-30
Latest Received Date:	N/A
Total Number of Reports:	802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04399962	2	2021-07-09	2021-08-26	MAH	MOD-2021-244510	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
77 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ATIVAN	Concomitant	NOT SPECIFIED	Unknown	0.5 Milligram	1 every 1 Days		Anxiety
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	Injection	Unknown	1.0 Dosage forms			COVID-19 immunisation
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	1.0 Dosage forms			COVID-19 immunisation
DILTIAZEM CD	Concomitant	Capsules					Prinzmetal angina, Blood pressure measurement
DILTIAZEM CD	Concomitant	CAPSULE, CONTROLLED-DELIVERY	Unknown	180.0 Milligram	2 every 1 Days		Prinzmetal angina, Blood pressure measurement

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ELIQUIS FILM COATED	Concomitant	Tablets	Unknown	5.0 Milligram	2 every 1 Days		Product used for unknown indication
FUROSEMIDE	Concomitant	NOT SPECIFIED	Unknown	20.0 Milligram	1 every 1 Days		Fluid retention
NITROGLYCERIN	Concomitant		Unknown				Product used for unknown indication
POTASSIUM	Concomitant	NOT SPECIFIED		20.0 Milliequivalents			Product used for unknown indication
POTASSIUM CHLORIDE	Concomitant		Unknown	20.0 Milliequivalents	1 every 1 Days		Mineral supplementation
SYMBICORT TURBUHALER	Concomitant	Powder	Intra-nasal				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arrhythmia	v.24.1	28 Days
Asthenia	v.24.1	
Asthma	v.24.1	28 Days
Chest pain	v.24.1	28 Days
Cough	v.24.1	28 Days
Dyspnoea	v.24.1	28 Days
Fatigue	v.24.1	
Inappropriate schedule of product administration	v.24.1	1 Days
Malaise	v.24.1	28 Days
Myocarditis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04400560	1	2021-07-09	2021-09-07	MAH	2021785094	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
77 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AMLODIPINE	Concomitant	Tablets					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
SANDOZ SOLIFENACIN	Concomitant	Tablets					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Myelodysplastic syndrome	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04400578	0	2021-07-09	2021-07-09	MAH	2021796599	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
63 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CELEBREX	Concomitant	Capsules	Oral				Depression
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthritis	v.24.1	
Diabetes mellitus	v.24.1	
Hypoaesthesia	v.24.1	
Myalgia	v.24.1	
Paraesthesia	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Sleep disorder	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04400617	1	2021-07-09	2021-09-14	MAH	2021782766	Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
31 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
HPV VACCINE	Concomitant	SUSPENSION INTRAMUSCULAR			Total	1.0 Days	Immunisation
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abortion spontaneous	v.24.1	
Inappropriate schedule of product administration	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:07:47 AM
Initial Received Date:	2021-06-16 to 2021-07-30
Latest Received Date:	N/A
Total Number of Reports:	802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04400845	1	2021-07-09	2021-08-23	MAH	2021787357	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
65 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Lipase increased	v.24.1	9 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04400992	0	2021-07-09	2021-07-09	MAH	2021640833	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
68 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AMLODIPINE	Concomitant	Tablets		5.0 Milligram			Blood pressure abnormal
ESCITALOPRAM	Concomitant	Tablets		20.0 Milligram			Anxiety
PANTOPRAZOLE	Concomitant	NOT SPECIFIED		40.0 Milligram			Hernia
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
ROSUVASTATIN	Concomitant	NOT SPECIFIED		40.0 Milligram			Blood cholesterol

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
C-reactive protein increased	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Peripheral swelling	v.24.1	
Pruritus	v.24.1	
Red blood cell sedimentation rate abnormal	v.24.1	
Urticaria	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04401203	0	2021-07-09	2021-07-09	MAH	CA2021148888	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
70 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown				Prophylaxis
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect		Unknown				Prophylaxis
SHINGRIX HERPES ZOSTER VACCINE (NON-LIVE RECOMBINANT, AS01B ADJUVANTED)	Suspect	Solution for injection	Unknown				Prophylaxis

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
SHINGRIX HERPES ZOSTER VACCINE (NON-LIVE RECOMBINANT, AS01B ADJUVANTED)	Suspect	SUSPENSION INTRAMUSCULAR	Unknown				Prophylaxis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Herpes zoster	v.24.1	
Vaccination failure	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04401208	1	2021-07-09	2021-08-27	MAH	2021805018	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
63 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
APO-PREDNISONE	Concomitant	Tablets					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
VALACYCLOVIR	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bell's palsy	v.24.1	-172

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:07:47 AM
Initial Received Date:	2021-06-16 to 2021-07-30
Latest Received Date:	N/A
Total Number of Reports:	802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04401404	0	2021-07-09	2021-07-09	MAH	2021796543	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
15 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Optic neuropathy	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04401427	1	2021-07-09	2021-07-13	MAH	2021796661	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
71 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Autoimmune disorder	v.24.1	
Blister	v.24.1	
Eczema	v.24.1	
Hypersensitivity	v.24.1	
Pruritus	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04401669	2	2021-07-09	2021-09-08	MAH	2021787730	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Eye disorder	v.24.1	
Head injury	v.24.1	-147
Headache	v.24.1	
Vision blurred	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04402326	0	2021-07-11	2021-07-11	MAH	2021746325	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
69 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
HYDROCHLOROTHIAZIDE/ OLMESARTAN MEDOXOMIL	Concomitant		Oral				Hypertension
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular			1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	2 Days
Blindness	v.24.1	
Change of bowel habit	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.24.1	
Hyperhidrosis	v.24.1	
Nausea	v.24.1	
Pain	v.24.1	
Syncope	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04402332	1	2021-07-11	2021-09-03	MAH	2021555493	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
55 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CLONAZEPAM	Concomitant	Tablets	Oral				Stress
OXYCONTIN	Concomitant	TABLET (EXTENDED-RELEASE)	Oral				Pain
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Months	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Burning sensation	v.24.1	
Condition aggravated	v.24.1	
Diarrhoea	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Drug hypersensitivity	v.24.1	
Hyperhidrosis	v.24.1	
Influenza like illness	v.24.1	1 Months
Pelvic pain	v.24.1	
Pyrexia	v.24.1	1 Months
Sarcoidosis	v.24.1	
Urinary incontinence	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04404375	1	2021-07-12	2021-07-15	MAH	MOD-2021-241636	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
37 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	1.0 Dosage forms		1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.24.1	1 Days
Hypoaesthesia	v.24.1	1 Days
Hypoaesthesia oral	v.24.1	1 Days
Palpitations	v.24.1	1 Days
Syncope	v.24.1	1 Days
Urticaria	v.24.1	1 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04404657	3	2021-07-12	2021-09-16	MAH	CA2021AMR123244	Study	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
89 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_02740774
Linked	E2B_02167711
Linked	
Linked	E2B_01588054
Linked	E2B_00897235
Linked	E2B_02481710
Linked	E2B_02740774
Linked	E2B_02167711
Linked	
Linked	E2B_01588054
Linked	E2B_00897235
Linked	E2B_02481710
Linked	E2B_02740774
Linked	E2B_02167711
Linked	
Linked	E2B_01588054

Record Type	Link AER** Number
Linked	E2B_00897235
Linked	E2B_02481710
Linked	E2B_02740774
Linked	E2B_02167711
Linked	
Linked	E2B_01588054
Linked	E2B_00897235
Linked	E2B_02481710

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				COVID-19 prophylaxis
MEPOLIZUMAB	Suspect		Subcutaneous	100.0 Milligram			Asthma
MEPOLIZUMAB	Suspect	Solution for injection in pre-filled syringe	Subcutaneous	100.0 Milligram			Asthma
MEPOLIZUMAB	Suspect	Powder for injection	Subcutaneous	100.0 Milligram			Asthma
MEPOLIZUMAB	Suspect	Solution for injection in pre-filled pen	Unknown	100.0 Milligram			Asthma

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cardiac pacemaker insertion	v.24.1	
Cardiovascular disorder	v.24.1	
Erythema	v.24.1	
Fall	v.24.1	
Herpes zoster	v.24.1	
Hip fracture	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Peripheral swelling	v.24.1	
Product dose omission issue	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04404900	0	2021-07-12	2021-07-12	MAH	2021A603021	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
58 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Product used for unknown indication
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Back pain	v.24.1	
Burning sensation	v.24.1	
Feeling hot	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hallucination	v.24.1	
Headache	v.24.1	1 Days
Hyperhidrosis	v.24.1	
Hypotonia	v.24.1	
Influenza like illness	v.24.1	
Interchange of vaccine products	v.24.1	
Off label use	v.24.1	
Pelvic pain	v.24.1	
Peripheral swelling	v.24.1	
Pyrexia	v.24.1	1 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04405218	3	2021-07-12	2021-08-26	MAH	2021A611708	Spontaneous	Consumer/other non health professional

Serious report?
Serious

Death:	No	**Disability:**	No	**Congenital Anomaly:**	No
Life Threatening:	Yes	**Hospitalization:**	Yes	**Other Medically Important Conditions:**	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
62 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Product used for unknown indication
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Contusion	v.24.1	
Energy increased	v.24.1	
Platelet count decreased	v.24.1	
Thrombosis	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
White blood cell count abnormal	v.24.1	
White blood cell count decreased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:07:47 AM
Initial Received Date:	2021-06-16 to 2021-07-30
Latest Received Date:	N/A
Total Number of Reports:	802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04406062	0	2021-07-12	2021-07-12	MAH	2021787712	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
56 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
SYNTHROID	Concomitant	NOT SPECIFIED	Unknown				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Adnexa uteri pain	v.24.1	14 Days
Arthralgia	v.24.1	24 Days
Deafness	v.24.1	
Dizziness	v.24.1	
Ear congestion	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Ear pain	v.24.1	
Gastrointestinal pain	v.24.1	
Therapeutic response unexpected	v.24.1	
Tinnitus	v.24.1	
Vertigo	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04406103	0	2021-07-12	2021-07-12	MAH	2021787789	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
72 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACEBUTOLOL	Concomitant	Tablets					
HYDRALAZINE HYDROCHLORIDE	Concomitant						
PERINDOPRIL ERBUMINE	Concomitant	Tablets					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.24.1	-174
Cough	v.24.1	-174

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dysphonia	v.24.1	-174
Eye swelling	v.24.1	-174
Inappropriate schedule of product administration	v.24.1	
Increased upper airway secretion	v.24.1	-174
Pain	v.24.1	-174
Swelling face	v.24.1	-174
Vomiting	v.24.1	-176

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04406152	1	2021-07-12	2021-08-20	MAH	2021805464	Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
33 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Condition aggravated	v.24.1	
Thrombotic thrombocytopenic purpura	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04406175	1	2021-07-12	2021-08-12	MAH	2021786329	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
16 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	000956180

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pneumothorax	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04406180	0	2021-07-12	2021-07-12	MAH	2021787561	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
34 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CELEBREX	Concomitant	Capsules	Unknown				
ESOMEPRAZOLE	Concomitant	NOT SPECIFIED	Unknown				
HUMIRA	Concomitant	SOLUTION SUBCUTANEOUS	Unknown				
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
TYLENOL	Concomitant	NOT SPECIFIED	Unknown				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Inappropriate schedule of product administration	v.24.1	
Pulmonary embolism	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04406191	1	2021-07-12	2021-07-30	MAH	2021796783	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
24 Years	Male		63 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Body temperature decreased	v.24.1	24 Hours
Chest discomfort	v.24.1	24 Hours
Chills	v.24.1	24 Hours
Confusional state	v.24.1	24 Hours
Hyperhidrosis	v.24.1	24 Hours
Inappropriate schedule of product administration	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Presyncope	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04406269	0	2021-07-12	2021-07-12	MAH	2021786091	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
47 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BETAHISTINE	Concomitant						
GRAVOL	Concomitant	NOT SPECIFIED					
MOTRIN [IBUPROFEN]	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
PREDNISONE	Concomitant	NOT SPECIFIED					
PROPRANOLOL HYDROCHLORIDE	Concomitant						
ROSUVASTATIN CALCIUM	Concomitant						
SENNOSIDES	Concomitant						
SERTRALINE HYDROCHLORIDE	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Ear discomfort	v.24.1	
Ear infection	v.24.1	
Head discomfort	v.24.1	
Headache	v.24.1	
Hypoaesthesia	v.24.1	
Migraine	v.24.1	1 Days
Paraesthesia oral	v.24.1	
Tinnitus	v.24.1	
Vertigo	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04406332	0	2021-07-12	2021-07-12	MAH	2021785980	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
64 Years	Female			Recovered/resolved with sequelae

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cellulitis	v.24.1	
Herpes zoster	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04406581	1	2021-07-12	2021-10-18	MAH	2021845865	Study	Other health professional

Serious report?	Death:	Disability:	Congenital Anomaly:
Serious	Yes	No	No
	Life Threatening: No	**Hospitalization:** No	**Other Medically Important Conditions:** No

Patient Information

Age	Gender	Height	Weight	Report Outcome
85 Years	Male			Fatal

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
ELIGARD	Suspect	POWDER FOR SUSPENSION, SUSTAINED-RELEASE	Subcutaneous	30.0 Milligram			Prostate cancer

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Disease progression	v.24.1	
Dizziness	v.24.1	
Fall	v.24.1	
Malaise	v.24.1	
Prostate cancer	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04406659	1	2021-07-12	2021-08-24	MAH	2021814134	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
63 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Months	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Optic ischaemic neuropathy	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04406746	1	2021-07-12	2021-08-23	MAH	2021785752	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
53 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MODAFINIL	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	-147
Delirium	v.24.1	-147
Fatigue	v.24.1	-147
Myalgia	v.24.1	-147
Paraesthesia	v.24.1	2190 Minutes

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pyrexia	v.24.1	-147
Vaccination site mass	v.24.1	-147
Vaccination site pain	v.24.1	-147

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04407065	0	2021-07-12	2021-07-12	MAH	2021786334	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
54 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MINERALS NOS/VITAMINS NOS	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
SALBUTAMOL SULFATE	Concomitant		Unknown				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Inappropriate schedule of product administration	v.24.1	
Ophthalmic herpes zoster	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04408110	0	2021-07-12	2021-07-12	MAH	2021785758	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
53 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Delirium	v.24.1	
Dizziness	v.24.1	
Fatigue	v.24.1	
Hallucination	v.24.1	
Hyperhidrosis	v.24.1	
Inappropriate schedule of product administration	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Limb discomfort	v.24.1	
Nausea	v.24.1	
Off label use	v.24.1	
Pain	v.24.1	
Pain in extremity	v.24.1	
Pyrexia	v.24.1	
Somnolence	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04408115	1	2021-07-12	2021-08-30	MAH	2021785773	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
47 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
KETOCONAZOLE	Concomitant	NOT SPECIFIED	Oral				Tinea infection
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Chest pain	v.24.1	
Dizziness	v.24.1	
Dyspnoea	v.24.1	
Fatigue	v.24.1	
Heart rate irregular	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Palpitations	v.24.1	4 Weeks
Syncope	v.24.1	
Vision blurred	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04410756	6	2021-07-13	2021-11-18	MAH	SB-2021-13058	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
24 Years	Female		55 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ATROVENT	Concomitant	NOT SPECIFIED	Unknown		As required		Product used for unknown indication
BENADRYL	Concomitant	NOT SPECIFIED	Unknown		As required		Product used for unknown indication
BUDESONIDE/FORMOTEROL FUMARATE	Concomitant		Unknown		As required		Product used for unknown indication
BUSCOPAN	Concomitant	NOT SPECIFIED	Unknown		As required		Product used for unknown indication
COVID-19 VACCINE	Suspect		Unknown				Product used for unknown indication

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
RENFLEXIS SINGLE USE VIAL	Suspect	Infusion	Unknown	400.0 Milligram	1 every 6 Weeks		Crohn's disease
RENFLEXIS SINGLE USE VIAL	Suspect	POWDER FOR SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	300.0 Milligram	1 every 6 Weeks		Crohn's disease

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.24.1	
Asthenia	v.24.1	
Chest discomfort	v.24.1	
Crohn's disease	v.24.1	
Feeling hot	v.24.1	
Foetal death	v.24.1	
Heart rate increased	v.24.1	
Maternal exposure during pregnancy	v.24.1	
Mental disorder	v.24.1	
Partner stress	v.24.1	
Physical assault	v.24.1	
Product use issue	v.24.1	
Psoriasis	v.24.1	
Rash	v.24.1	
Stress	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04410794	0	2021-07-13	2021-07-13	MAH	2021A615259	Spontaneous	Consumer/other non health professional

Serious report?	Death:	Disability:	Congenital Anomaly:
Serious	Yes	No	No
	Life Threatening: No	**Hospitalization:** No	**Other Medically Important Conditions:** No

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male			Fatal

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.5 ml			Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Death	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04412550	1	2021-07-13	2021-08-25	MAH	2021796821	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
43 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CANNABIDIOL	Concomitant		Oral	10.0 Milligram	3 every 1 Days		Affective disorder
CANNABIS SATIVA	Concomitant			3.0 Milligram			Sleep disorder
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Coordination abnormal	v.24.1	
Discomfort	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Drooling	v.24.1	
Dysphonia	v.24.1	
Fatigue	v.24.1	
Fatigue	v.24.1	
Feeling abnormal	v.24.1	
Gait disturbance	v.24.1	
Heart rate increased	v.24.1	
Hyperhidrosis	v.24.1	
Hypoaesthesia	v.24.1	
Hypoaesthesia	v.24.1	
Hypoaesthesia	v.24.1	
Hypoaesthesia	v.24.1	-126
Hypokinesia	v.24.1	
Limb discomfort	v.24.1	
Malaise	v.24.1	
Mobility decreased	v.24.1	
Mobility decreased	v.24.1	
Muscle contractions involuntary	v.24.1	
Muscle discomfort	v.24.1	
Musculoskeletal disorder	v.24.1	
Musculoskeletal stiffness	v.24.1	
Panic attack	v.24.1	2 Minutes
Paraesthesia	v.24.1	
Paraesthesia	v.24.1	-125
Photosensitivity reaction	v.24.1	
Sensory loss	v.24.1	
Sleep disorder	v.24.1	
Temperature regulation disorder	v.24.1	
Tremor	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04412644	1	2021-07-13	2021-08-27	MAH	2021807494	Spontaneous	Consumer/other non health professional

Serious report?
Serious

Death:	No	**Disability:**	No	**Congenital Anomaly:**	No
Life Threatening:	No	**Hospitalization:**	No	**Other Medically Important Conditions:**	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
47 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_04412680
Linked	E2B_04412680
Linked	E2B_04412680
Linked	E2B_04412680
Linked	E2B_04412680
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Months	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.24.1	
Heart rate abnormal	v.24.1	
Syncope	v.24.1	
Tremor	v.24.1	
Vertigo	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04412668	1	2021-07-13	2021-07-28	MAH	2021862322	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male	51 Centimeter	3 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_04421161
Linked	E2B_04421161
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Transplacental	0.3 ml	Total	1.0 Days	COVID-19 immunisation
SYNTHROID	Concomitant	NOT SPECIFIED	Transplacental		1 every 1 Days		Hypothyroidism
VALACYCLOVIR	Concomitant	NOT SPECIFIED	Transplacental		1 every 1 Days		Antibiotic therapy

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Maternal exposure during pregnancy	v.24.1	
Meconium aspiration syndrome	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Neonatal respiratory distress	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04412808	0	2021-07-13	2021-07-13	MAH	2021798331	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
63 Years	Female	160 Centimeter	64 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dyspnoea	v.24.1	
Panic reaction	v.24.1	
Pneumonia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04413035	0	2021-07-13	2021-07-13	MAH	2021456562	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
71 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ATORVASTATIN	Concomitant	Tablets		10.0 Milligram			
FELODIPINE	Concomitant	TABLET (EXTENDED-RELEASE)					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.24.1	
Hypertension	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04413055	1	2021-07-13	2021-09-04	MAH	2021684220	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
43 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ESTRADIOL	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
PROGESTERONE	Concomitant						
ROSUVASTATIN	Concomitant	NOT SPECIFIED	Subcutaneous				
VENLAFAXINE	Concomitant						
VITAMIN D3	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypokinesia	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Illness	v.24.1	3 Days
Inappropriate schedule of product administration	v.24.1	
Lymphadenopathy	v.24.1	8 Days
Postmenopausal haemorrhage	v.24.1	5 Days
Synovial cyst	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04413058	0	2021-07-13	2021-07-13	MAH	2021664847	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
27 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Palpitations	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04413061	1	2021-07-13	2021-08-20	MAH	2021569024	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Movement disorder	v.24.1	
Myalgia	v.24.1	
Rheumatoid arthritis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04413317	1	2021-07-13	2021-07-26	MAH	MOD-2021-252120	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
84 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	1.0 Dosage forms			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Erythema	v.24.1	
Myocardial infarction	v.24.1	
Product dose omission issue	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:07:47 AM
Initial Received Date:	2021-06-16 to 2021-07-30
Latest Received Date:	N/A
Total Number of Reports:	802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04413625	2	2021-07-13	2021-08-20	MAH	2021839209	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
81 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ATORVASTATIN	Concomitant	Tablets	Oral				Hypercholesterolaemia
FINASTERIDE	Concomitant	Tablets	Oral	5.0 Milligram			Prostatomegaly
HYDROCHLOROTHIAZIDE	Concomitant	Tablets	Oral				Fluid retention
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
RAMIPRIL	Concomitant	NOT SPECIFIED	Oral				Hypertension
RAPAFLO	Concomitant	NOT SPECIFIED	Oral				Prostatomegaly

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood pressure fluctuation	v.24.1	
Burning sensation	v.24.1	
Chest pain	v.24.1	
Dizziness	v.24.1	
Dyspnoea	v.24.1	
Gait disturbance	v.24.1	
Head discomfort	v.24.1	
Headache	v.24.1	
Hot flush	v.24.1	
Hypotension	v.24.1	
Malaise	v.24.1	
Myocardial infarction	v.24.1	
Paraesthesia	v.24.1	
Petechiae	v.24.1	
Vaccination site pain	v.24.1	1 Hours

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04414621	0	2021-07-13	2021-07-13	MAH	2021807508	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
45 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Heavy menstrual bleeding	v.24.1	
Thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04415120	0	2021-07-14	2021-07-14	MAH	MOD-2021-253264	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	1.0 Dosage forms			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bell's palsy	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04415276	0	2021-07-14	2021-07-14	MAH	MOD-2021-253015	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
67 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	Injection	Unknown	1.0 Dosage forms			COVID-19 immunisation
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Unknown	1.0 Dosage forms			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cerebrovascular accident	v.24.1	
Gait disturbance	v.24.1	
Hypoaesthesia	v.24.1	
Inappropriate schedule of product administration	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04419973	0	2021-07-14	2021-07-14	MAH	2021841391	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
ORENCIA	Suspect		Subcutaneous	125.0 Milligram	1 every 1 Weeks		Rheumatoid arthritis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Atrial fibrillation	v.24.1	
Back pain	v.24.1	
Musculoskeletal stiffness	v.24.1	
Pain in extremity	v.24.1	
Vitamin B12 decreased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04420103	0	2021-07-14	2021-07-14	MAH	2021806602	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
56 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
TYLENOL	Concomitant	NOT SPECIFIED	Oral				Back pain

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bell's palsy	v.24.1	
Hypoaesthesia	v.24.1	
Paraesthesia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04420118	1	2021-07-14	2021-08-26	MAH	2021806490	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypoaesthesia	v.24.1	
Loss of consciousness	v.24.1	
Mobility decreased	v.24.1	
Paralysis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04420158	1	2021-07-14	2021-08-27	MAH	2021807206	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
39 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Cold sweat	v.24.1	
Dizziness	v.24.1	
Dysphagia	v.24.1	
Feeling abnormal	v.24.1	
Feeling hot	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypoaesthesia	v.24.1	
Lack of spontaneous speech	v.24.1	
Ligament sprain	v.24.1	
Movement disorder	v.24.1	
Peripheral coldness	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04420596	1	2021-07-14	2021-08-26	MAH	2021815208	Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
73 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Seizure	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04420682	1	2021-07-14	2021-07-29	MAH	2021828604	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
66 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_04421112

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ALENDRONATE SODIUM	Concomitant		Oral	70.0 Milligram	1 every 1 Weeks		Osteoporosis
CITALOPRAM	Concomitant		Oral				Depression
GABAPENTIN	Concomitant	NOT SPECIFIED	Oral				Back pain
LORAZEPAM	Concomitant	NOT SPECIFIED	Oral				Anxiety
MORPHINE	Concomitant	NOT SPECIFIED	Oral				Back pain
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypoaesthesia	v.24.1	
Myocardial infarction	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04420851	1	2021-07-14	2021-08-27	MAH	2021822157	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
28 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
TRAZODONE	Concomitant						
VENLAFAXINE	Concomitant						
VYVANSE	Concomitant	Capsules					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Amnesia	v.24.1	
Cognitive disorder	v.24.1	
Dysarthria	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Sensory level abnormal	v.24.1	
Vertigo	v.24.1	
Vision blurred	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04420903	1	2021-07-14	2021-08-27	MAH	2021821156	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
50 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETYLSALICYLIC ACID	Concomitant	NOT SPECIFIED	Unknown				
DIOVAN	Concomitant	NOT SPECIFIED					
HCTZ	Concomitant	NOT SPECIFIED	Unknown				
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
SYNTHROID	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Ear disorder	v.24.1	
Fatigue	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.24.1	
Impaired driving ability	v.24.1	
Loss of personal independence in daily activities	v.24.1	
Lymphadenopathy	v.24.1	
Nausea	v.24.1	
Vertigo	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04420972	0	2021-07-14	2021-07-14	MAH	2021815346	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
49 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Appendicitis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04421039	0	2021-07-14	2021-07-14	MAH	2021815881	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
40 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BORAGO OFFICINALIS/FISH OIL/LINUM USITATISSIMUM	Concomitant						
NABILONE	Concomitant	NOT SPECIFIED		1.0 Milligram	every 1 Days		
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
VITAMIN D3	Concomitant	Capsules					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.24.1	
Fatigue	v.24.1	
Pain	v.24.1	
Pyrexia	v.24.1	
Syncope	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04421059	0	2021-07-14	2021-07-14	MAH	2021815892	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
57 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
POTASSIUM CHLORIDE	Concomitant	NOT SPECIFIED	Oral	20.0 Milliequivalents			Hypokalaemia

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Inappropriate schedule of product administration	v.24.1	
Monoplegia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04421110	0	2021-07-14	2021-07-14	MAH	2021820846	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain upper	v.24.1	
Leiomyoma	v.24.1	
Renal disorder	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04421116	1	2021-07-14	2021-08-11	MAH	2021816193	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
42 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CIPRALEX [ESCITALOPRAM]	Concomitant						
ETHINYL ESTRADIOL/LEVONORGESTREL	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Angina pectoris	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	1410 Minutes
Chest pain	v.24.1	
Dyspnoea	v.24.1	
Pain in extremity	v.24.1	1410 Minutes

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04421161	0	2021-07-14	2021-07-14	MAH	2021846573	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
31 Years	Female	179 Centimeter	49 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_04412668
Linked	E2B_04412668

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Total	1.0 Days	COVID-19 immunisation
SYNTHROID	Concomitant	NOT SPECIFIED	Oral		1 every 1 Days		Hypothyroidism
VALACYCLOVIR	Concomitant	NOT SPECIFIED	Oral		1 every 1 Days		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypertension	v.24.1	
Maternal exposure during pregnancy	v.24.1	
Meconium in amniotic fluid	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Prolonged pregnancy	v.24.1	1 Days
Vaccination site pain	v.24.1	24 Hours

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04421478	2	2021-07-14	2021-09-13	MAH	2021806635	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
45 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Guillain-Barre syndrome	v.24.1	
Loss of personal independence in daily activities	v.24.1	
Muscular weakness	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04421485	1	2021-07-14	2021-09-15	MAH	2021807347	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
39 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
VITAMINS NOS	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Altered state of consciousness	v.24.1	
Asthenia	v.24.1	
Chills	v.24.1	
Cold sweat	v.24.1	
Dysarthria	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dysphagia	v.24.1	
Dyspnoea	v.24.1	
Hypoaesthesia	v.24.1	
Joint dislocation	v.24.1	
Mobility decreased	v.24.1	
Paraesthesia	v.24.1	
Paralysis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04421627	1	2021-07-14	2021-07-28	MAH	2021799770	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
68 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETYLSALICYLIC ACID	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
ROSUVASTATIN CALCIUM	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Polymyalgia rheumatica	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04421634	0	2021-07-14	2021-07-14	MAH	2021785870	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
54 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
TEVA-DULOXETINE	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Appendicitis	v.24.1	1 Days
Fatigue	v.24.1	
Influenza like illness	v.24.1	4 Days
Malaise	v.24.1	
Neck pain	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pain	v.24.1	
Pain in extremity	v.24.1	
Sleep disorder	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04423470	0	2021-07-15	2021-07-15	MAH	BL-2021-023961	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
66 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AVAMYS	Concomitant	SPRAY, METERED DOSE					Product used for unknown indication
BETAMETHASONE DIPROPIONATE	Concomitant						Product used for unknown indication
CHADOX1 NCOV-19	Suspect		Unknown			1.0 Days	COVID-19 immunisation
CODEINE	Concomitant						Product used for unknown indication
COVERSYL	Concomitant	Tablets					Product used for unknown indication

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Unknown			1.0 Days	COVID-19 immunisation
EZETIMIBE	Concomitant	Tablets					Product used for unknown indication
GLICLAZIDE	Concomitant	Tablets					Product used for unknown indication
METFORMIN HYDROCHLORIDE/SITAGLIPTIN PHOSPHATE MONOHYDRATE	Concomitant						Product used for unknown indication
PANTOPRAZOLE	Concomitant	NOT SPECIFIED					Product used for unknown indication
ROSUVASTATIN	Concomitant	NOT SPECIFIED	Subcutaneous				Product used for unknown indication
SALBUTAMOL	Concomitant	NOT SPECIFIED					Product used for unknown indication
SILIQ 2 SINGLE USE PREFILLED SYRINGES	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous	210.0 Milligram	1 every 1 Weeks	1.0 Months	Psoriasis
SILIQ 2 SINGLE USE PREFILLED SYRINGES	Suspect	Solution for injection	Subcutaneous	210.0 Milligram	1 every 2 Weeks		Psoriasis
TRAMADOL	Concomitant						Product used for unknown indication
ZOPICLONE	Concomitant	Tablets					Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Illness	v.24.1	1 Days
Pericarditis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04425833	1	2021-07-15	2021-08-10	MAH	2021814922	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
18 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dysmenorrhoea	v.24.1	
Headache	v.24.1	
Heavy menstrual bleeding	v.24.1	
Nausea	v.24.1	
Pain in extremity	v.24.1	
Tremor	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:07:47 AM
Initial Received Date:	2021-06-16 to 2021-07-30
Latest Received Date:	N/A
Total Number of Reports:	802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04425965	0	2021-07-15	2021-07-15	MAH	2021828977	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
43 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pericarditis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04426144	0	2021-07-15	2021-07-15	MAH	2021822189	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
30 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BLEXTEN	Concomitant	Tablets					
CROMOLYN SODIUM	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Guillain-Barre syndrome	v.24.1	
Hypoaesthesia	v.24.1	
Myelitis transverse	v.24.1	
Prostatitis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04426584	0	2021-07-15	2021-07-15	MAH	2021814833	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
53 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PAROXETINE	Concomitant	Tablets		20.0 Milligram			
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown			1.0 Days	COVID-19 immunisation
QUETIAPINE	Concomitant	Tablets		150.0 Milligram			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Ataxia	v.24.1	
Confusional state	v.24.1	
Dysarthria	v.24.1	
Fatigue	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Gait disturbance	v.24.1	
Gingival bleeding	v.24.1	
Headache	v.24.1	
Monoplegia	v.24.1	
Myalgia	v.24.1	
Mydriasis	v.24.1	
Nausea	v.24.1	
Neck pain	v.24.1	
Peripheral venous disease	v.24.1	
Thrombocytopenia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04426617	1	2021-07-15	2021-08-27	MAH	2021828951	Spontaneous	Consumer/other non health professional

Serious report?
Serious

Death:	No	**Disability:**	No	**Congenital Anomaly:**	No
Life Threatening:	No	**Hospitalization:**	No	**Other Medically Important Conditions:**	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
44 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ERGOCALCIFEROL	Concomitant						
FISH OIL	Concomitant	Capsule					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation
VENLAFAXINE HYDROCHLORIDE	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.24.1	
Hyperhidrosis	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypoaesthesia	v.24.1	
Pain in extremity	v.24.1	
Paraesthesia	v.24.1	
Syncope	v.24.1	
Tremor	v.24.1	
Vaccination site pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04426690	0	2021-07-15	2021-07-15	MAH	2021820502	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
65 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
LACOSAMIDE	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
WARFARIN	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04426778	1	2021-07-15	2021-08-24	MAH	2021822160	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
24 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BILASTINE	Concomitant		Oral				Hypersensitivity
BREO ELLIPTA	Concomitant	INHALATION	Inhalation				Asthma
FLUTICASONE PROPIONATE	Concomitant		Intra-nasal				Rhinitis allergic
MARVELON 21	Concomitant	Tablets	Oral				Contraception
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Inappropriate schedule of product administration	v.24.1	
Pericarditis	v.24.1	-180

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04426809	0	2021-07-15	2021-07-15	MAH	2021829127	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
53 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BIOTIN/FOLIC ACID/IODINE/PANTOTHENIC ACID/PYRIDOXINE HYDROCHLORIDE/VITAMIN A/VITAMIN B12/VITAMIN C/VITAMIN D/VITAMIN E/ZINC	Concomitant						
CIPROFLOXACIN HYDROCHLORIDE	Concomitant			10.0 Milligram			
LOSEC [OMEPRAZOLE]	Concomitant			20.0 Milligram			
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.24.1	
Disturbance in attention	v.24.1	
Fatigue	v.24.1	
Feeling abnormal	v.24.1	
Mental impairment	v.24.1	
Movement disorder	v.24.1	
Pain in extremity	v.24.1	
Postmenopausal haemorrhage	v.24.1	
Vaccination site pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04426966	1	2021-07-15	2021-08-27	MAH	2021815091	Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
17 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cough	v.24.1	
Dyspnoea	v.24.1	
Hodgkin's disease	v.24.1	
Pericardial effusion	v.24.1	-159

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:07:47 AM
Initial Received Date:	2021-06-16 to 2021-07-30
Latest Received Date:	N/A
Total Number of Reports:	802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04427032	0	2021-07-15	2021-07-15	MAH	2021820126	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
31 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abortion spontaneous	v.24.1	
Maternal exposure during pregnancy	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04427095	0	2021-07-15	2021-07-15	MAH	2021813073	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
40 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal distension	v.24.1	
Abdominal pain	v.24.1	
Arthralgia	v.24.1	
Back pain	v.24.1	
Dysstasia	v.24.1	
Gait disturbance	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Gastrointestinal inflammation	v.24.1	
Hypokinesia	v.24.1	
Inflammation	v.24.1	
Loss of personal independence in daily activities	v.24.1	
Myalgia	v.24.1	
Pain	v.24.1	
Spinal osteoarthritis	v.24.1	
Spondylitis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04427194	1	2021-07-15	2021-08-25	MAH	2021839609	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
18 Years	Male		56 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AZATHIOPRINE	Concomitant	Tablets	Unknown	100.0 Milligram			
INFLIXIMAB	Suspect	NOT SPECIFIED	Intravenous (not otherwise specified)	5.0 mg/kg			Crohn's disease
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Crohn's disease	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04427218	1	2021-07-15	2021-08-26	MAH	2021829018	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
53 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BIOTIN/FOLIC ACID/IODINE/PANTOTHENIC ACID/PYRIDOXINE HYDROCHLORIDE/VITAMIN A/VITAMIN B12/VITAMIN C/VITAMIN D/VITAMIN E/ZINC	Concomitant						
CIPROFLOXACIN HYDROCHLORIDE	Concomitant			10.0 Milligram			
LOSEC [OMEPRAZOLE]	Concomitant			20.0 Milligram			
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Postmenopausal haemorrhage	v.24.1	
Vaccination site movement impairment	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04427500	0	2021-07-15	2021-07-15	MAH	2021BI01029435	Study	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				COVID-19 prophylaxis
TYSABRI	Suspect	Unknown	Intravenous (not otherwise specified)	300.0 Milligram	1 every 5 Weeks	2.0 Years	Multiple sclerosis
TYSABRI	Suspect	Unknown	Intravenous (not otherwise specified)	300.0 Milligram	1 every 6 Weeks	102.0 Days	Multiple sclerosis
TYSABRI	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	300.0 Milligram	1 every 4 Weeks	900.0 Days	Multiple sclerosis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Diabetes mellitus	v.24.1	
Prescribed underdose	v.24.1	
Vaccination complication	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04427510	1	2021-07-16	2021-08-13	MAH	21K-028-3949883-00	Study	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
67 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular			1.0 Days	COVID-19 prophylaxis
COVID-19 VACCINE	Suspect		Intramuscular			1.0 Days	COVID-19 prophylaxis
HUMIRA	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous	40.0 Milligram	1 every 2 Weeks	-38.0	Colitis ulcerative
HUMIRA	Suspect	Solution for injection in pre-filled pen	Subcutaneous	40.0 Milligram	1 every 1 Weeks		Colitis ulcerative

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Colitis ulcerative	v.24.1	
Colitis ulcerative	v.24.1	-90
Drug level decreased	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Faecal volume decreased	v.24.1	
Haemorrhage	v.24.1	-90
Therapeutic product effect delayed	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04427596	0	2021-07-16	2021-07-16	MAH	21K-028-3981724-00	Study	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
46 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	
Linked	
Linked	E2B_02823449
Linked	
Linked	
Linked	
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular			0.0	COVID-19 prophylaxis
HUMIRA	Suspect	Solution for injection in pre-filled pen	Subcutaneous	40.0 Milligram	1 every 2 Weeks		Rheumatoid arthritis
HUMIRA	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous	40.0 Milligram	1 every 2 Weeks		Rheumatoid arthritis

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
HUMIRA	Suspect	Solution for injection in pre-filled pen	Subcutaneous	40.0 Milligram	1 every 2 Weeks		Rheumatoid arthritis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Drug resistance	v.24.1	
Illness	v.24.1	
Pyrexia	v.24.1	
Rheumatoid arthritis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04430622	4	2021-07-16	2021-12-23	MAH	MYERS SQUIBB COMPANY	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
65 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				COVID-19 immunisation
ORENCIA	Suspect		Intravenous (not otherwise specified)	1000.0 Milligram	1 every 4 Weeks		Rheumatoid arthritis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arrhythmia	v.24.1	
Blood glucose abnormal	v.24.1	
Intentional product use issue	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04430804	1	2021-07-16	2021-08-19	MAH	2021821390	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
89 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CHLORTHALIDONE	Concomitant	Tablets					Blood pressure abnormal
CLOPIDOGREL	Concomitant	Tablets					Anticoagulant therapy
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
ROSUVASTATIN	Concomitant	NOT SPECIFIED					Blood cholesterol abnormal

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	0 Months
Bone pain	v.24.1	
Dizziness	v.24.1	
Ear discomfort	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Mobility decreased	v.24.1	
Myalgia	v.24.1	0 Months
Pain in extremity	v.24.1	
Tinnitus	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04430946	1	2021-07-16	2021-08-31	MAH	2021845622	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
PROBIOTICS NOS	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anxiety	v.24.1	
Facial paralysis	v.24.1	
Hypoaesthesia	v.24.1	
Nerve injury	v.24.1	
Paraesthesia	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Vitamin B12 deficiency	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04431036	1	2021-07-16	2021-08-27	MAH	2021829771	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
46 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Months	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal distension	v.24.1	
Abdominal pain	v.24.1	
Diarrhoea	v.24.1	
Diarrhoea haemorrhagic	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:07:47 AM
Initial Received Date:	2021-06-16 to 2021-07-30
Latest Received Date:	N/A
Total Number of Reports:	802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04431220	1	2021-07-16	2021-08-13	MAH	2021830266	Spontaneous	Consumer/other non health professional

Serious report?	Death:	Yes	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
85 Years	Male			Fatal

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Inappropriate schedule of product administration	v.24.1	
Myocardial infarction	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04431345	1	2021-07-16	2021-08-26	MAH	2021830834	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
40 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BUPROPION	Concomitant						
CANDESARTAN	Concomitant						
CETIRIZINE HYDROCHLORIDE	Concomitant						
ESCITALOPRAM	Concomitant	Tablets					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Heavy menstrual bleeding	v.24.1	-104

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04431361	0	2021-07-16	2021-07-16	MAH	2021830826	Spontaneous	Other health professional

Serious report?	Death:	Disability:	Congenital Anomaly:
Serious	No	Yes	No
	Life Threatening: No	**Hospitalization:** Yes	**Other Medically Important Conditions:** No

Patient Information

Age	Gender	Height	Weight	Report Outcome
55 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Discomfort	v.24.1	
Dysphagia	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Loss of personal independence in daily activities	v.24.1	
Muscular weakness	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Musculoskeletal stiffness	v.24.1	
Myositis	v.24.1	
Pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04431362	0	2021-07-16	2021-07-16	MAH	2021830493	Spontaneous	Consumer/other non health professional

Serious report?	Death:	Disability:	Congenital Anomaly:
Serious	Yes	No	No
	Life Threatening: Yes	**Hospitalization:** Yes	**Other Medically Important Conditions:** No

Patient Information

Age	Gender	Height	Weight	Report Outcome
54 Years	Male			Fatal

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
RISPERIDONE	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Acute respiratory distress syndrome	v.24.1	
Headache	v.24.1	
Neck pain	v.24.1	
Oxygen saturation decreased	v.24.1	
Pneumonia	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pulmonary oedema	v.24.1	
Spinal cord infection	v.24.1	
Swelling	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04431375	0	2021-07-16	2021-07-16	MAH	2021846262	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
33 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Vaginal haemorrhage	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:07:47 AM
Initial Received Date:	2021-06-16 to 2021-07-30
Latest Received Date:	N/A
Total Number of Reports:	802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04431429	1	2021-07-16	2021-09-01	MAH	2021840745	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Jaundice	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:07:47 AM
Initial Received Date:	2021-06-16 to 2021-07-30
Latest Received Date:	N/A
Total Number of Reports:	802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04431447	1	2021-07-16	2021-08-31	MAH	2021845704	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
65 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
INSULIN	Concomitant	GLOBULES ORAL					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pericarditis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04431448	0	2021-07-16	2021-07-16	MAH	2021830735	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
67 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ALPRAZOLAM	Concomitant	Tablets		5.0 Milligram			
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
SERTRALINE	Concomitant	Capsules		100.0 Milligram	2 every 1 Days		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Diarrhoea	v.24.1	
Dysphonia	v.24.1	
Fatigue	v.24.1	5 Days
Headache	v.24.1	183

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Inappropriate schedule of product administration	v.24.1	
Lymphadenopathy	v.24.1	
Musculoskeletal stiffness	v.24.1	
Myalgia	v.24.1	
Nausea	v.24.1	
Oropharyngeal pain	v.24.1	
Pain	v.24.1	
Vaccination site pain	v.24.1	2 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04431449	1	2021-07-16	2021-08-26	MAH	2021830712	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
51 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Confusional state	v.24.1	
Disturbance in attention	v.24.1	
Fatigue	v.24.1	
Memory impairment	v.24.1	
Mental impairment	v.24.1	
Somnolence	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Speech disorder	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04431493	0	2021-07-16	2021-07-16	MAH	2021830674	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
75 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASAPHEN	Concomitant	NOT SPECIFIED					
BISOPROLOL FUMARATE	Concomitant						
PERINDOPRIL	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
ROSUVASTATIN CALCIUM	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Herpes zoster	v.24.1	
Inappropriate schedule of product administration	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04431529	1	2021-07-16	2021-07-16	MAH	2021830201	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
27 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MEZAVANT ALSO KNOWN AS MESALAMINE	Concomitant	TABLET (DELAYED AND EXTENDED RELEASE)					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
PREVACID	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood pressure increased	v.24.1	
C-reactive protein increased	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest discomfort	v.24.1	
Dizziness	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Myocarditis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04431810	0	2021-07-16	2021-07-16	MAH	2021829833	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
41 Years	Female	152 Centimeter	48 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Total	1.0 Days	COVID-19 immunisation
VITAMINS NOS	Concomitant		Oral				Prenatal care, Pregnancy

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abortion spontaneous	v.24.1	
Vaccination site pain	v.24.1	2 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04432267	0	2021-07-16	2021-07-16	MAH	2021830210	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
25 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Heavy menstrual bleeding	v.24.1	
Presyncope	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04432372	0	2021-07-16	2021-07-16	MAH	MOD-2021-255931	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
67 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Unknown	1.0 Dosage forms			COVID-19 immunisation
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	Injection	Unknown	1.0 Dosage forms			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Mobility decreased	v.24.1	
Noninfective encephalitis	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Paralysis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04432556	2	2021-07-16	2021-08-12	MAH	2021830713	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
40 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
LEVOTHYROXINE SODIUM	Concomitant		Oral	100.0 Microgram	every 1 Days		Hypothyroidism
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Facial paresis	v.24.1	270 Minutes
Hypoaesthesia	v.24.1	387 Minutes
Sensory loss	v.24.1	270 Minutes

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04432570	2	2021-07-16	2021-09-01	MAH	2021841317	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
51 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Uterine leiomyoma	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04433426	0	2021-07-18	2021-07-18	MAH	2021831532	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
52 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anxiety	v.24.1	
Suicidal ideation	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04436598	0	2021-07-19	2021-07-19	MAH	20210717379	Study	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
47 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown			1.0 Months	COVID-19 prophylaxis
REMICADE	Suspect	POWDER FOR SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)				Colitis ulcerative

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Colitis ulcerative	v.24.1	
Endocarditis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04436833	0	2021-07-19	2021-07-19	MAH	2021M1041865	Published	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
51 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Duplicate	E2B_03903049

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CLOZAPINE	Suspect		Unknown	500.0 Milligram	1 every 1 Days		Schizoaffective disorder
CLOZAPINE	Suspect		Unknown	300.0 Milligram	1 every 1 Days		Schizoaffective disorder
FENOFIBRATE	Concomitant	NOT SPECIFIED	Unknown				
LINAGLIPTIN	Concomitant		Unknown				
METFORMIN	Concomitant		Unknown				
PANTOPRAZOLE	Concomitant	NOT SPECIFIED	Unknown				
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown				COVID-19 immunisation
VALPROATE SEMISODIUM	Concomitant		Unknown				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Antipsychotic drug level increased	v.24.1	
C-reactive protein increased	v.24.1	
Delirium	v.24.1	
Fall	v.24.1	
Incontinence	v.24.1	
Monocyte count increased	v.24.1	
Neutrophil count increased	v.24.1	
Pneumonia	v.24.1	
White blood cell count increased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:07:47 AM
Initial Received Date:	2021-06-16 to 2021-07-30
Latest Received Date:	N/A
Total Number of Reports:	802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04436974	1	2021-07-19	2021-08-26	MAH	2021612261	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
54 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Postmenopausal haemorrhage	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04436977	2	2021-07-19	2021-08-26	MAH	2021840921	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
39 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASA	Concomitant	NOT SPECIFIED	Oral				Cerebrovascular accident
BIPHENTIN	Concomitant	CAPSULE, EXTENDED RELEASE	Oral				Meningioma
CELECOXIB	Concomitant						
ELMIRON	Concomitant	Capsules					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
SYNTHROID	Concomitant	NOT SPECIFIED	Oral	50.0 Milligram			Hypothyroidism
TYLENOL	Concomitant	NOT SPECIFIED	Oral	500.0 Milligram	As required		Pain

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Haemarthrosis	v.24.1	13 Days
Menstrual disorder	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04436986	1	2021-07-19	2021-09-13	MAH	2021831290	Spontaneous	Physician

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
83 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
FOSAMAX	Concomitant	Tablets		70.0 Milligram	1 every 1 Weeks		
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cerebral disorder	v.24.1	
Feeling abnormal	v.24.1	
Memory impairment	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04436993	0	2021-07-19	2021-07-19	MAH	2021846497	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
69 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dyspnoea	v.24.1	
Fluid retention	v.24.1	
Myocarditis	v.24.1	
Polymyalgia rheumatica	v.24.1	
Pruritus	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04436997	1	2021-07-19	2021-09-15	MAH	2021846052	Spontaneous	Other health professional

Serious report?	Death:	Disability:	Congenital Anomaly:
Serious	Yes	No	No
	Life Threatening: No	**Hospitalization:** No	**Other Medically Important Conditions:** No

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Fatal

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.24.1	
Drug ineffective	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04436999	1	2021-07-19	2021-08-27	MAH	2021861642	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
28 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
SYNTHROID	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood pressure decreased	v.24.1	
Chills	v.24.1	
Headache	v.24.1	
Loss of consciousness	v.24.1	1 Days
Pain	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Presyncope	v.24.1	
Seizure	v.24.1	
Syncope	v.24.1	
Urticaria	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04437023	1	2021-07-19	2021-08-26	MAH	2021887390	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
61 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
DYMISTA SUSPENSION	Concomitant	SPRAY, METERED DOSE	Intra-nasal				Hypersensitivity
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
PROLIA PRE-FILLED SYRINGE. PRESERVATIVE-FREE.	Concomitant	SOLUTION SUBCUTANEOUS	Subcutaneous				Osteoporosis
SALBUTAMOL	Concomitant	NOT SPECIFIED	Intra-nasal				Asthma
VALTREX	Concomitant		Oral				Herpes simplex

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Contusion	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Deep vein thrombosis	v.24.1	
Headache	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Musculoskeletal stiffness	v.24.1	
Thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04437338	1	2021-07-19	2021-08-06	MAH	2021862036	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
39 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASA	Concomitant	NOT SPECIFIED	Oral				Cerebrovascular accident
BIPHENTIN	Concomitant	CAPSULE, EXTENDED RELEASE	Oral				Meningioma
CELECOXIB	Concomitant						
ELMIRON	Concomitant	Capsules					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular			1.0 Days	COVID-19 immunisation
SYNTHROID	Concomitant	NOT SPECIFIED	Oral	50.0 Milligram			Hypothyroidism
TYLENOL	Concomitant	NOT SPECIFIED	Oral	500.0 Milligram	As required		Pain

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Haematoma	v.24.1	23505 Minutes
Inappropriate schedule of product administration	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04439483	0	2021-07-20	2021-07-20	MAH	21K-028-3992546-00	Study	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
62 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular			1.0 Days	COVID-19 prophylaxis
HUMIRA	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous	40.0 Milligram	1 every 2 Weeks	337.0 Days	Rheumatoid arthritis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Drug ineffective	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04440383	1	2021-07-20	2021-08-04	MAH	MOD-2021-258741	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
67 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Unknown	1.0 Dosage forms			COVID-19 immunisation
QUERCETIN/VITAMIN C	Concomitant		Oral	500.0 Milligram	1 every 1 Days		Urticaria, Flushing
VITAMIN C [ASCORBIC ACID]	Concomitant		Oral	1000.0 Milligram	1 every 1 Days		Urticaria, Flushing
ZINC	Concomitant	NOT SPECIFIED	Oral	25.0 Milligram			Urticaria, Flushing

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.24.1	
Arthralgia	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Erythema	v.24.1	
Swelling	v.24.1	
Vaccination site bruising	v.24.1	
Vaccination site induration	v.24.1	
Vaccination site pruritus	v.24.1	30 Days
Vaccination site swelling	v.24.1	
Vaccination site vesicles	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04440861	1	2021-07-20	2021-08-26	MAH	2021846578	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CANNABIS SATIVA	Concomitant		Inhalation				Nausea
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bladder pain	v.24.1	
Condition aggravated	v.24.1	
Crystal urine present	v.24.1	
Nephrolithiasis	v.24.1	
Renal pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04440877	0	2021-07-20	2021-07-20	MAH	2021846195	Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
26 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.24.1	
Myocarditis	v.24.1	
Pericarditis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04440908	0	2021-07-20	2021-07-20	MAH	2021846555	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
24 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
VITAMIN C [ASCORBIC ACID]	Concomitant						
VITAMIN D [COLECALCIFEROL]	Concomitant						
ZINC	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cardiac flutter	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.24.1	
Pruritus	v.24.1	
Rash	v.24.1	
Rash macular	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04441165	0	2021-07-20	2021-07-20	MAH	MOD-2021-259183	Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
38 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Unknown	1.0 Dosage forms			COVID-19 immunisation
IRON	Concomitant		Unknown	1.0 Dosage forms			Product used for unknown indication
TOZINAMERAN	Suspect		Unknown	1.0 Dosage forms			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Interchange of vaccine products	v.24.1	
Pericarditis	v.24.1	
Wrong product administered	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04441568	0	2021-07-20	2021-07-20	MAH	20210633992	Study	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
67 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	
Linked	
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown			1.0 Days	COVID-19 prophylaxis
STELARA	Suspect	Solution for infusion	Intravenous (not otherwise specified)	390.0 Milligram			Crohn's disease
STELARA	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous	90.0 Milligram	1 every 8 Weeks		Crohn's disease

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Crohn's disease	v.24.1	
Epistaxis	v.24.1	
Fatigue	v.24.1	
Feeling abnormal	v.24.1	
Headache	v.24.1	
Hyperhidrosis	v.24.1	2 Months
Illness	v.24.1	
Infusion related reaction	v.24.1	1 Days
Malaise	v.24.1	
Movement disorder	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04441825	1	2021-07-20	2021-08-30	MAH	2021841307	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
69 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
NIFEDIPINE	Concomitant	NOT SPECIFIED	Oral				Heart rate irregular
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
ROSUVASTATIN	Concomitant	NOT SPECIFIED	Oral				Blood cholesterol

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	1 Days
Hand fracture	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Myalgia	v.24.1	1 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04441828	0	2021-07-20	2021-07-20	MAH	2021851135	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
41 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown			1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bell's palsy	v.24.1	
Hypoaesthesia	v.24.1	
Muscular weakness	v.24.1	
Palpitations	v.24.1	
Paraesthesia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04441830	0	2021-07-20	2021-07-20	MAH	2021840179	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
29 Years	Female			Recovered/resolved with sequelae

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
IRON	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain lower	v.24.1	
Calculus urinary	v.24.1	
Dysstasia	v.24.1	
Nephrolithiasis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04441836	0	2021-07-20	2021-07-20	MAH	2021841310	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
69 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
NIFEDIPINE	Concomitant	NOT SPECIFIED	Oral				Heart rate irregular
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
ROSUVASTATIN	Concomitant	NOT SPECIFIED	Oral				Blood cholesterol abnormal
TETANUS VACCINE	Concomitant		Intramuscular		Total	1.0 Days	Hand fracture

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Loss of control of legs	v.24.1	
Movement disorder	v.24.1	
Muscular weakness	v.24.1	
Myalgia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04441837	0	2021-07-20	2021-07-20	MAH	2021629644	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
40 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Gait inability	v.24.1	
Hand deformity	v.24.1	
Joint swelling	v.24.1	
Mobility decreased	v.24.1	
Musculoskeletal stiffness	v.24.1	
Pain	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pain in extremity	v.24.1	24 Hours
Peripheral swelling	v.24.1	
Polyarthritis	v.24.1	
Tenosynovitis	v.24.1	
Wheelchair user	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04441838	1	2021-07-20	2021-08-02	MAH	2021845706	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
29 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Nephrolithiasis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04441840	1	2021-07-20	2021-09-03	MAH	2021850469	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
55 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
INFLIXIMAB	Concomitant		Intravenous (not otherwise specified)	5.0 mg/kg			Crohn's disease
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
PREDNISONE	Concomitant	NOT SPECIFIED		1.0 Dosage forms			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal distension	v.24.1	
Abdominal pain	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anxiety	v.24.1	
Constipation	v.24.1	
Obstruction	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04441932	0	2021-07-20	2021-07-20	MAH	2021845966	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
81 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypoaesthesia	v.24.1	
Partial seizures	v.24.1	28 Days
Sensory disturbance	v.24.1	28 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04442332	1	2021-07-20	2021-08-12	MAH	2021853896	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
53 Years	Female	183 Centimeter	75 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Fatigue	v.24.1	
Haemorrhage	v.24.1	
Headache	v.24.1	
Lower limb fracture	v.24.1	
Muscle spasms	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Myalgia	v.24.1	
Off label use	v.24.1	
Pain	v.24.1	
Pain in extremity	v.24.1	
Pelvic fracture	v.24.1	
Product contamination	v.24.1	
Pyrexia	v.24.1	
Vaccination site bruising	v.24.1	
Vaccination site pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04443532	0	2021-07-20	2021-07-20	MAH	MOD-2021-259939	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Unknown	1.0 Dosage forms			COVID-19 immunisation
TOZINAMERAN	Concomitant		Unknown	1.0 Dosage forms			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Haemorrhage	v.24.1	
Off label use	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:07:47 AM
Initial Received Date:	2021-06-16 to 2021-07-30
Latest Received Date:	N/A
Total Number of Reports:	802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04443629	1	2021-07-20	2021-09-15	MAH	2021849827	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
45 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Hypoaesthesia	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Multiple sclerosis	v.24.1	
Pain	v.24.1	
Pain in extremity	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04443932	0	2021-07-21	2021-07-21	MAH	CA2021AMR086207	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
74 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_02253114
Linked	
Linked	E2B_03464823
Linked	E2B_02567536
Linked	E2B_02352995

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				COVID-19 prophylaxis
MEPOLIZUMAB	Suspect	Solution for injection in pre-filled pen	Subcutaneous	100.0 Milligram			Asthma
MEPOLIZUMAB	Suspect		Subcutaneous	100.0 Milligram			Asthma
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown				COVID-19 prophylaxis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthritis	v.24.1	
Muscular weakness	v.24.1	
Pain in extremity	v.24.1	
Peripheral swelling	v.24.1	
Rheumatoid arthritis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04444435	1	2021-07-21	2021-10-20	MAH	2020SA187156	Study	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
28 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ALEMTUZUMAB	Suspect		Intravenous drip	12.0 Milligram	1 every 1 Days	3.0 Days	Relapsing-remitting multiple sclerosis
AZATHIOPRINE SODIUM	Concomitant		Unknown				
CALCIUM	Concomitant	NOT SPECIFIED	Unknown				
CETIRIZINE HYDROCHLORIDE	Concomitant		Unknown	10.0 Milligram			
COVID-19 VACCINE	Suspect		Unknown				COVID-19 immunisation
ENTOCORT	Concomitant	CAPSULE, SUSTAINED-RELEASE	Unknown				
FINGOLIMOD HYDROCHLORIDE	Concomitant		Unknown				

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
METHYLPREDNISOLONE	Concomitant		Unknown	500.0 Milligram			
RANITIDINE	Concomitant		Unknown	150.0 Milligram			
TYLENOL	Concomitant	NOT SPECIFIED	Unknown	1.0 Gram			
VALACYCLOVIR	Concomitant	NOT SPECIFIED	Unknown	500.0 Milligram			
VITAMIN D	Concomitant	NOT SPECIFIED	Unknown				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Contusion	v.24.1	
Immune thrombocytopenia	v.24.1	
Influenza	v.24.1	
Menstruation irregular	v.24.1	
Nasopharyngitis	v.24.1	1 Days
Pain	v.24.1	1 Days
Platelet count decreased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04448271	0	2021-07-21	2021-07-21	MAH	MOD-2021-259348	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
69 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	Injection	Unknown	1.0 Dosage forms			COVID-19 immunisation
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Unknown	1.0 Dosage forms			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain upper	v.24.1	
Chest pain	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fall	v.24.1	
Gait disturbance	v.24.1	
Gallbladder rupture	v.24.1	
Inappropriate schedule of product administration	v.24.1	1 Days
Infection	v.24.1	
Liver abscess	v.24.1	
Nausea	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04448357	1	2021-07-21	2021-07-23	MAH	2021A630801	Published	Physician

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
48 Years	Female	175 Centimeter	68 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_04459398
Linked	E2B_04462386
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Product used for unknown indication
CITALOPRAM	Concomitant						
LEVETIRACETAM	Concomitant	Tablets	Unknown				
PRAVASTATIN	Concomitant						
TAMOXIFEN	Concomitant	Tablets					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Aortic thrombosis	v.24.1	
Immune thrombocytopenia	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Leg amputation	v.24.1	
Peripheral artery thrombosis	v.24.1	
Peripheral artery thrombosis	v.24.1	
Peripheral ischaemia	v.24.1	
Stress cardiomyopathy	v.24.1	
Subclavian artery thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04449281	0	2021-07-21	2021-07-21	MAH	20210528035	Study	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
55 Years	Female		162 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				COVID-19
REMICADE	Suspect	POWDER FOR SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)				Crohn's disease

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Erythema	v.24.1	
Fluid retention	v.24.1	
Oedema peripheral	v.24.1	
Secretion discharge	v.24.1	
Skin ulcer	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Vaginal haemorrhage	v.24.1	
Weight increased	v.24.1	
Wound infection	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04449870	1	2021-07-21	2021-08-23	MAH	2021852357	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
32 Years	Female		75 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain upper	v.24.1	1 Days
Diarrhoea	v.24.1	1 Days
Discharge	v.24.1	
Heavy menstrual bleeding	v.24.1	
Menstrual disorder	v.24.1	7 Days
Vomiting	v.24.1	1 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04449906	0	2021-07-21	2021-07-21	MAH	2021846365	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
61 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
FLUOXETINE	Concomitant	NOT SPECIFIED					
METFORMIN	Concomitant						
MRNA-1273 SARS-COV-2	Suspect	NOT SPECIFIED	Unknown		Total	1.0 Days	COVID-19 immunisation
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
SYNTHROID	Concomitant	NOT SPECIFIED					
TOPIRAMATE	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Burning sensation	v.24.1	
Interchange of vaccine products	v.24.1	
Neuralgia	v.24.1	
Off label use	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04449920	1	2021-07-21	2021-08-03	MAH	2021841366	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
84 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain	v.24.1	
Diarrhoea	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Malaise	v.24.1	
Nausea	v.24.1	
Pyrexia	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Venous thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04449922	0	2021-07-21	2021-07-21	MAH	2021846371	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
53 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AMLODIPINE BESILATE	Concomitant		Oral	5.0 Milligram	every 1 Days		Blood pressure increased
COVERSYL [PERINDOPRIL ARGININE]	Concomitant		Oral	2.0 Milligram	every 1 Days		Blood pressure increased
LIPITOR	Concomitant	NOT SPECIFIED		10.0 Milligram	every 1 Days		Pericarditis
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total		COVID-19 immunisation
QUETIAPINE FUMARATE	Concomitant			125.0 Milligram	every 1 Days		Depression
SINGULAIR	Concomitant	NOT SPECIFIED	Oral				Allergy prophylaxis
VENLAFAXINE HYDROCHLORIDE	Concomitant		Oral				Depression

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.24.1	
Pericarditis	v.24.1	
Rash	v.24.1	0 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04449935	2	2021-07-21	2021-09-06	MAH	2021850489	Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
79 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ALLOPURINOL	Concomitant	Tablets					
DILTIAZEM	Concomitant						
FENOFIBRATE	Concomitant	NOT SPECIFIED					
GLICLAZIDE	Concomitant	Tablets					
METFORMIN	Concomitant						
METOPROLOL	Concomitant						
NITROGLYCERIN	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
ROSUVASTATIN	Concomitant	NOT SPECIFIED					
SITAGLIPTIN	Concomitant						
TELMISARTAN	Concomitant	Tablets					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Back pain	v.24.1	
Facial paralysis	v.24.1	
Gait inability	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Musculoskeletal pain	v.24.1	
Pain in extremity	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:07:47 AM
Initial Received Date:	2021-06-16 to 2021-07-30
Latest Received Date:	N/A
Total Number of Reports:	802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04449963	1	2021-07-21	2021-08-05	MAH	2021855415	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
29 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bell's palsy	v.24.1	
Eyelid function disorder	v.24.1	
Facial pain	v.24.1	
Hypoaesthesia	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Mastication disorder	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04449970	1	2021-07-21	2021-09-03	MAH	2021861198	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
60 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
LAX-A-DAY	Concomitant	POWDER FOR SOLUTION ORAL					
PANTOPRAZOLE SODIUM	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain	v.24.1	
Flatulence	v.24.1	
Haematochezia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04450009	0	2021-07-21	2021-07-21	MAH	2021845815	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
30 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CLONAZEPAM	Concomitant	Tablets					
IBUPROFEN	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
TYLENOL	Concomitant	NOT SPECIFIED					
VITAMIN D	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Chest discomfort	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.24.1	
Condition aggravated	v.24.1	
Dehydration	v.24.1	
Fatigue	v.24.1	
Hypoaesthesia	v.24.1	
Insomnia	v.24.1	
Musculoskeletal stiffness	v.24.1	
Myalgia	v.24.1	
Neuralgia	v.24.1	
Paraesthesia	v.24.1	
Peripheral swelling	v.24.1	
Peripheral vascular disorder	v.24.1	
Sciatica	v.24.1	
Spinal pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04450439	0	2021-07-21	2021-07-21	MAH	2021530301	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
31 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ADVAIR	Concomitant	NOT SPECIFIED			As required		
CONCERTA	Concomitant	TABLET (EXTENDED-RELEASE)		54.0 Milligram	1 every 1 Days		
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
SERTRALINE	Concomitant	Capsules		150.0 Milligram	1 every 1 Days		
SYNTHROID	Concomitant	NOT SPECIFIED		1.2 Microgram	1 every 1 Days		
VENTOLIN [SALBUTAMOL]	Concomitant				As required		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.24.1	1 Days

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dysphagia	v.24.1	1 Days
Dyspnoea	v.24.1	1 Days
Lymph node pain	v.24.1	1 Days
Lymphadenopathy	v.24.1	1 Days
Pain	v.24.1	1 Days
Panic attack	v.24.1	1 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04450459	0	2021-07-21	2021-07-21	MAH	2021607052	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
64 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
VITAMINS NOS	Concomitant		Oral				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Oral herpes	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04450484	0	2021-07-21	2021-07-21	MAH	2021694595	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain upper	v.24.1	
Chest pain	v.24.1	
Discomfort	v.24.1	
Palpitations	v.24.1	
Paraesthesia	v.24.1	
Vein rupture	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04450488	1	2021-07-21	2021-09-01	MAH	2021846030	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
83 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypoaesthesia	v.24.1	
Partial seizures	v.24.1	
Sensory disturbance	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04450579	1	2021-07-21	2021-09-01	MAH	2021868763	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Feeling abnormal	v.24.1	
Headache	v.24.1	
Hypoaesthesia	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Limb discomfort	v.24.1	
Muscular weakness	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Myalgia	v.24.1	
Nausea	v.24.1	
Oropharyngeal pain	v.24.1	
Paraesthesia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04450630	1	2021-07-21	2021-09-06	MAH	2021856213	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
32 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
LORAZEPAM	Concomitant	NOT SPECIFIED					
METFORMIN	Concomitant						
MOTRIN [IBUPROFEN]	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
TRAZODONE	Concomitant						
VENLAFAXINE HYDROCHLORIDE	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Inappropriate schedule of product administration	v.24.1	
Muscle spasms	v.24.1	
Muscular weakness	v.24.1	
Musculoskeletal stiffness	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04450704	0	2021-07-21	2021-07-21	MAH	2021856664	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
38 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
VITAMIN C [ASCORBIC ACID]	Concomitant						
VITAMIN D	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.24.1	
Dyspnoea	v.24.1	
Fibrin D dimer increased	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pericarditis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04451560	0	2021-07-21	2021-07-21	MAH	2021855097	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
49 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BETAHISTINE	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown			1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dysphagia	v.24.1	4 Hours
Hypoaesthesia	v.24.1	24 Hours
Inappropriate schedule of product administration	v.24.1	
Pharyngeal hypoaesthesia	v.24.1	24 Hours
Pharyngeal swelling	v.24.1	4 Hours

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Swollen tongue	v.24.1	4 Hours

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04451602	1	2021-07-21	2021-09-07	MAH	2021855461	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Interstitial lung disease	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04451619	0	2021-07-21	2021-07-21	MAH	2021855384	Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
22 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Months	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Seizure	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04451797	0	2021-07-21	2021-07-21	MAH	2021746193	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
78 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AMLODIPINE	Concomitant	Tablets	Oral				Hypertension
ASA	Concomitant	NOT SPECIFIED	Oral				
ATORVASTATIN	Concomitant	Tablets	Oral				Blood cholesterol increased
NADOLOL	Concomitant	Tablets	Oral				Hypertension
PERINDOPRIL	Concomitant		Oral				Hypertension
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
VENLAFAXINE HYDROCHLORIDE	Concomitant		Oral				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood pressure increased	v.24.1	1 Days
Inappropriate schedule of product administration	v.24.1	
Pruritus	v.24.1	
Rash papular	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04452496	1	2021-07-22	2021-08-03	MAH	CA2021AMR156205	Study	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
73 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	E2B_02220773
Linked	E2B_02960544
Linked	E2B_02635649
Linked	E2B_03005487
Linked	E2B_04632031
Linked	
Linked	
Linked	
Linked	
Linked	E2B_02220773
Linked	E2B_02960544
Linked	E2B_02635649
Linked	E2B_03005487
Linked	
Linked	

Record Type	Link AER** Number
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				Product used for unknown indication, COVID-19 prophylaxis
COVID-19 VACCINE	Suspect		Unknown				Product used for unknown indication, COVID-19 prophylaxis
MEPOLIZUMAB	Suspect		Subcutaneous	100.0 Milligram			Asthma

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Epistaxis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04455177	0	2021-07-22	2021-07-22	MAH	2021611640	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
38 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
VITAMINS NOS	Concomitant		Oral				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dysmenorrhoea	v.24.1	
Menstruation irregular	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04455180	0	2021-07-22	2021-07-22	MAH	2021612871	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
15 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
LOLO	Concomitant		Oral				Menstruation irregular, Heavy menstrual bleeding, Contraception, Acne
LOLO	Concomitant		Oral				Menstruation irregular, Heavy menstrual bleeding, Contraception, Acne

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
LOLO	Concomitant		Oral				Menstruation irregular, Heavy menstrual bleeding, Contraception, Acne
LOLO	Concomitant	Tablets	Oral				Menstruation irregular, Heavy menstrual bleeding, Contraception, Acne
OMNARIS	Concomitant	SPRAY, METERED DOSE				22.0 Days	Rhinitis
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular			1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Balance disorder	v.24.1	
Chills	v.24.1	
Dizziness	v.24.1	
Dizziness postural	v.24.1	
Gait disturbance	v.24.1	
Nausea	v.24.1	
Vision blurred	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04455222	1	2021-07-22	2021-09-01	MAH	2021855459	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
60 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Limb discomfort	v.24.1	
Paraesthesia	v.24.1	
Vaccination site pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04455335	0	2021-07-22	2021-07-22	MAH	2021855114	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
26 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AVIANE 21	Concomitant	Tablets					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
SPIRONOLACTONE	Concomitant	Tablets					
TOPIRAMATE	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04455412	0	2021-07-22	2021-07-22	MAH	2021861977	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
56 Years	Female			Recovered/resolved with sequelae

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown				COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Loss of consciousness	v.24.1	
Vertigo	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04456032	0	2021-07-22	2021-07-22	MAH	202100929789	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
52 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
TYLENOL	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hepatic pain	v.24.1	
Inappropriate schedule of product administration	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04456281	1	2021-07-22	2021-08-20	MAH	2021880945	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
52 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain	v.24.1	
Artery dissection	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Mesenteric artery thrombosis	v.24.1	
Mesenteric haematoma	v.24.1	
Off label use	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

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Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04456357	1	2021-07-22	2021-08-20	MAH	2021870197	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
65 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CELEBREX	Concomitant	Capsules		200.0 Milligram			
METFORMIN	Concomitant			500.0 Milligram			
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
PREGABALIN	Concomitant	Capsules		75.0 Milligram			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bell's palsy	v.24.1	-199
Facial paralysis	v.24.1	-186
Inappropriate schedule of product administration	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04456566	1	2021-07-22	2021-09-06	MAH	2021862100	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
79 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ALLOPURINOL	Concomitant	Tablets	Oral				Prophylaxis
LODIPINE [AMLODIPINE BESILATE]	Concomitant		Oral				Blood pressure abnormal
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
PRAVASTATIN	Concomitant		Oral				Blood cholesterol increased

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Gait inability	v.24.1	
Joint swelling	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04456567	1	2021-07-22	2021-07-27	MAH	2021854789	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
31 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dysmenorrhoea	v.24.1	
Heavy menstrual bleeding	v.24.1	
Menstrual disorder	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04456580	2	2021-07-22	2021-09-06	MAH	2021861155	Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
62 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Rheumatoid arthritis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:07:47 AM
Initial Received Date:	2021-06-16 to 2021-07-30
Latest Received Date:	N/A
Total Number of Reports:	802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04456645	0	2021-07-22	2021-07-22	MAH	2021862285	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
52 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hepatic pain	v.24.1	
Weight decreased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:07:47 AM
Initial Received Date:	2021-06-16 to 2021-07-30
Latest Received Date:	N/A
Total Number of Reports:	802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04457732	3	2021-07-23	2021-10-04	MAH	2873325	Study	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CEFADROXIL	Concomitant	NOT SPECIFIED	Unknown	500.0 Milligram			
COVID-19 VACCINE	Suspect		Unknown				Product used for unknown indication
OCRELIZUMAB	Suspect		Intravenous (not otherwise specified)	300.0 Milligram	1 every 2 Weeks		Relapsing-remitting multiple sclerosis
OCRELIZUMAB	Suspect	Solution for infusion	Intravenous (not otherwise specified)	600.0 Milligram	1 every 6 Months		Relapsing-remitting multiple sclerosis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cellulitis	v.24.1	
Lymphadenopathy	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04459281	2	2021-07-23	2021-08-11	MAH	2021A622477	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
55 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Product used for unknown indication
MRNA-1273 SARS-COV-2	Suspect	NOT SPECIFIED	Intramuscular				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Chest discomfort	v.24.1	
Chest pain	v.24.1	
Dizziness	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Guillain-Barre syndrome	v.24.1	
Headache	v.24.1	
Hypoaesthesia	v.24.1	
Interchange of vaccine products	v.24.1	
Limb discomfort	v.24.1	
Neck pain	v.24.1	
Off label use	v.24.1	
Paraesthesia	v.24.1	4 Weeks
Sensation of blood flow	v.24.1	
Throat irritation	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04459575	1	2021-07-23	2021-07-28	MAH	CA2021AMR157705	Study	Other health professional

Serious report?	Death:	Disability:	Congenital Anomaly:
Serious	Yes	No	No
	Life Threatening: No	**Hospitalization:** No	**Other Medically Important Conditions:** No

Patient Information

Age	Gender	Height	Weight	Report Outcome
56 Years	Female			Fatal

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_03809929
Linked	
Linked	
Linked	E2B_03809929

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				COVID-19 prophylaxis
MEPOLIZUMAB	Suspect		Subcutaneous	100.0 Milligram			Asthma
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown				COVID-19 prophylaxis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthma	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Product dose omission issue	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04460706	0	2021-07-23	2021-07-23	MAH	2021887274	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
36 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown			1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dysmenorrhoea	v.24.1	
Fatigue	v.24.1	
Haemorrhage	v.24.1	
Headache	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Nausea	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Vaccination site pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04460798	1	2021-07-23	2021-08-06	MAH	2021879660	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
60 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AMLODIPINE BESILATE	Concomitant		Oral	5.0 Milligram	every 1 Days		Hypertension
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
ROSUVASTATIN CALCIUM	Concomitant		Oral	5.0 Milligram	every 1 Days		Blood cholesterol increased

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	
Headache	v.24.1	
Hypersomnia	v.24.1	
Mobility decreased	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pain in extremity	v.24.1	
Pain in extremity	v.24.1	
Paraesthesia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04460851	1	2021-07-23	2021-09-06	MAH	2021868859	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
59 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dehydration	v.24.1	
Diarrhoea	v.24.1	
Dizziness	v.24.1	
Fatigue	v.24.1	
Headache	v.24.1	
Nausea	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04460941	1	2021-07-23	2021-09-03	MAH	2021862294	Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.24.1	
Decreased appetite	v.24.1	
Fatigue	v.24.1	
Hyperhidrosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04460946	0	2021-07-23	2021-07-23	MAH	2021862108	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
53 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CITALOPRAM	Concomitant		Oral				Anxiety
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypoaesthesia	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Pain in extremity	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04460981	0	2021-07-23	2021-07-23	MAH	2021574860	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ESCITALOPRAM OXALATE	Concomitant		Oral				
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
VITAMINS NOS	Concomitant		Oral				Supplementation therapy

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Gait inability	v.24.1	
Pain in extremity	v.24.1	
Thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04461078	1	2021-07-23	2021-09-09	MAH	2021887267	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
60 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Inappropriate schedule of product administration	v.24.1	
Vaccination site cellulitis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04461833	1	2021-07-23	2021-09-02	MAH	2021880508	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
74 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETYLSALICYLIC ACID	Concomitant				every 1 Days		
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
VITAMIN D	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Constipation	v.24.1	1 Months
Fatigue	v.24.1	
Gastritis	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Gastrointestinal disorder	v.24.1	4 Days
Headache	v.24.1	
Loss of personal independence in daily activities	v.24.1	
Nausea	v.24.1	
Somnolence	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04461990	0	2021-07-23	2021-07-23	MAH	2021887235	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
32 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Off label use	v.24.1	
Product use issue	v.24.1	
Vaginal haemorrhage	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04462025	0	2021-07-23	2021-07-23	MAH	2021887049	Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
51 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bradycardia	v.24.1	1 Minutes

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04462192	1	2021-07-23	2021-08-06	MAH	2021868507	Spontaneous	Physician

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
57 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blindness unilateral	v.24.1	
Inappropriate schedule of product administration	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04462386	0	2021-07-23	2021-07-23	MAH	2021A630726	Published	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
45 Years	Female	160 Centimeter	61 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Duplicate	E2B_02697894
Linked	E2B_04448357
Linked	E2B_04520531

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Adrenal haemorrhage	v.24.1	
Carotid artery thrombosis	v.24.1	
Cerebral haemorrhage	v.24.1	
Cerebral venous sinus thrombosis	v.24.1	
Confusional state	v.24.1	
Depressed level of consciousness	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypotension	v.24.1	
Immune thrombocytopenia	v.24.1	
Pelvic venous thrombosis	v.24.1	
Pulmonary embolism	v.24.1	
Renal infarct	v.24.1	
Vertebral artery thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04463684	0	2021-07-24	2021-07-24	MAH	21K-028-3993355-00	Study	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
30 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular			1.0 Months	COVID-19 prophylaxis
HUMIRA	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous	40.0 Milligram	1 every 2 Weeks	11.0 Months	Ankylosing spondylitis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Back pain	v.24.1	
Pain	v.24.1	
Tonsillitis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04465073	0	2021-07-26	2021-07-26	MAH	MOD-2021-094554	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
35 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	0.5 ml			COVID-19 immunisation
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	Injection		0.5 ml			COVID-19 immunisation
IRON	Concomitant		Oral				Iron deficiency
MINERALS NOS/VITAMINS NOS	Concomitant		Oral				Prenatal care

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abortion spontaneous	v.24.1	1 Days
Exposure during pregnancy	v.24.1	1 Days
Vaccination site pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04465594	1	2021-07-26	2021-08-24	MAH	CA2021AMR159020	Study	Consumer/other non health professional

Serious report?
Serious

Death:	No	**Disability:**	No	**Congenital Anomaly:**	No
Life Threatening:	No	**Hospitalization:**	Yes	**Other Medically Important Conditions:**	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
79 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	
Linked	
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				COVID-19 prophylaxis
MEPOLIZUMAB	Suspect		Subcutaneous	100.0 Milligram			Asthma

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fall	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Sleep terror	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04466176	1	2021-07-26	2021-10-25	MAH	21K-028-3997649-00	Study	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
51 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular			1.0 Days	COVID-19 immunisation
COVID-19 VACCINE	Suspect		Intramuscular			1.0 Days	COVID-19 immunisation
HUMIRA	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous	40.0 Milligram	1 every 2 Weeks	-81.0	Crohn's disease
HUMIRA	Suspect	Solution for injection in pre-filled pen	Subcutaneous	40.0 Milligram	1 every 2 Weeks		Crohn's disease

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blister	v.24.1	
Crohn's disease	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dry skin	v.24.1	
Faeces discoloured	v.24.1	
Frequent bowel movements	v.24.1	
Furuncle	v.24.1	
Hyperaesthesia	v.24.1	
Intentional product misuse	v.24.1	
Intestinal resection	v.24.1	
Nausea	v.24.1	
Pain	v.24.1	
Pruritus	v.24.1	
Rash	v.24.1	
Rash macular	v.24.1	
Skin exfoliation	v.24.1	
Skin lesion	v.24.1	
Skin ulcer	v.24.1	
Skin ulcer	v.24.1	
Therapeutic product effect decreased	v.24.1	
Wound complication	v.24.1	
Wound haemorrhage	v.24.1	
Wound secretion	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04466849	0	2021-07-26	2021-07-26	MAH	2021887750	Spontaneous	Physician

Serious report?	Death:	Yes	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
24 Years	Male			Fatal

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown				COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Death	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04466955	0	2021-07-26	2021-07-26	MAH	2021887685	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
39 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Burning sensation	v.24.1	
Diarrhoea	v.24.1	
Fatigue	v.24.1	
Headache	v.24.1	
Nausea	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Weight decreased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04466961	1	2021-07-26	2021-08-25	MAH	202100917565	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
43 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Deep vein thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04468435	0	2021-07-26	2021-07-26	MAH	2021901338	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
47 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Conjunctivitis bacterial	v.24.1	
Dry eye	v.24.1	
Eye infection viral	v.24.1	
Keratitis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04470011	0	2021-07-27	2021-07-27	MAH	MOD-2021-155148	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
60 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AMLODIPINE	Concomitant	Tablets	Unknown				Hypertension
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	Injection	Intramuscular	1.0 Dosage forms			
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect			1.0 Dosage forms			
METOPROLOL	Concomitant		Unknown				Hypertension
OMEPRAZOLE	Concomitant		Unknown				Product used for unknown indication

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ROSUVASTATIN CALCIUM	Concomitant		Unknown				Product used for unknown indication
TELMISARTAN	Concomitant	Tablets	Unknown				Hypertension

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain	v.24.1	2 Days
Anger	v.24.1	
Chills	v.24.1	2 Days
Depressed level of consciousness	v.24.1	2 Days
Diarrhoea	v.24.1	2 Days
Disorientation	v.24.1	2 Days
Dysphonia	v.24.1	2 Days
Dyspnoea	v.24.1	2 Days
Feeling hot	v.24.1	2 Days
Headache	v.24.1	
Hyperhidrosis	v.24.1	2 Days
Malaise	v.24.1	2 Days
Mood altered	v.24.1	
Myalgia	v.24.1	
Nausea	v.24.1	2 Days
Pain in extremity	v.24.1	
Pyrexia	v.24.1	2 Days
Retching	v.24.1	1 Days
Sleep disorder	v.24.1	2 Days
Thinking abnormal	v.24.1	
Tremor	v.24.1	
Vomiting	v.24.1	2 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04470654	0	2021-07-27	2021-07-27	MAH	MOD-2021-265786	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
82 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	1.0 Dosage forms			COVID-19 immunisation
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	Injection	Intramuscular	1.0 Dosage forms			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Colon cancer	v.24.1	
Condition aggravated	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Inappropriate schedule of product administration	v.24.1	1 Days
Pain in extremity	v.24.1	
Peripheral swelling	v.24.1	
Rheumatoid arthritis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04471187	1	2021-07-27	2021-09-16	MAH	2021886205	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
17 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Loss of consciousness	v.24.1	
Pneumonia aspiration	v.24.1	7 Days
Seizure	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04471215	0	2021-07-27	2021-07-27	MAH	2021887131	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Neuromyopathy	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04471595	2	2021-07-27	2021-09-21	MAH	CA2021AMR160136	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
62 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	
Linked	
Linked	E2B_02294831
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	E2B_02294831
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	

Record Type	Link AER** Number
Linked	E2B_02294831
Linked	
Linked	
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				COVID-19 prophylaxis
MEPOLIZUMAB	Suspect		Subcutaneous	100.0 Milligram			Product used for unknown indication, Asthma
MEPOLIZUMAB	Suspect	Powder for injection	Subcutaneous	100.0 Milligram			Product used for unknown indication, Asthma
PREDNISONE	Suspect	NOT SPECIFIED	Unknown				Product used for unknown indication
VENTOLIN	Suspect	NOT SPECIFIED	Unknown				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaemia	v.24.1	
Contusion	v.24.1	
Cough	v.24.1	
Dizziness	v.24.1	
Drug ineffective	v.24.1	
Dyspnoea	v.24.1	
Dyspnoea exertional	v.24.1	
Fatigue	v.24.1	
Haemorrhage	v.24.1	
Spontaneous haemorrhage	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04471793	1	2021-07-27	2021-09-03	MAH	2021886167	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
43 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Appendicitis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04471800	0	2021-07-27	2021-07-27	MAH	2021886302	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
55 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Burning sensation	v.24.1	
Dysgeusia	v.24.1	
Fatigue	v.24.1	
Formication	v.24.1	
Pruritus	v.24.1	
Vaccination site erythema	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Vaccination site pain	v.24.1	
Vaccination site rash	v.24.1	
Vaccination site urticaria	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04471829	1	2021-07-27	2021-09-14	MAH	2021887119	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
73 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CETIRIZINE	Concomitant		Oral				Hypersensitivity
LORAZEPAM	Concomitant		Oral				Anxiety
METFORMIN	Concomitant		Oral				Hypertension
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Herpes zoster	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Joint swelling	v.24.1	2 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04471830	0	2021-07-27	2021-07-27	MAH	2021907531	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
45 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
IBUPROFEN	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
SUMATRIPTAN	Concomitant	NOT SPECIFIED					
VITAMIN C [ASCORBIC ACID]	Concomitant						
VITAMIN D [COLECALCIFEROL]	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.24.1	36 Hours
Fatigue	v.24.1	36 Hours
Hallucination	v.24.1	36 Hours
Headache	v.24.1	36 Hours
Inappropriate schedule of product administration	v.24.1	
Insomnia	v.24.1	36 Hours
Myalgia	v.24.1	36 Hours
Pyrexia	v.24.1	36 Hours
Vaccination site pain	v.24.1	
Vomiting	v.24.1	36 Hours

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04471833	1	2021-07-27	2021-09-14	MAH	2021893312	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Papilloma viral infection	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04471837	1	2021-07-27	2021-09-14	MAH	2021887712	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
52 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Condition aggravated	v.24.1	
Fatigue	v.24.1	
Mast cell activation syndrome	v.24.1	
Multiple chemical sensitivity	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04471838	0	2021-07-27	2021-07-27	MAH	2021892794	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
39 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
INSULIN	Concomitant	GLOBULES ORAL	Intramuscular				Diabetes mellitus
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
RAMIPRIL	Concomitant	NOT SPECIFIED	Oral				Blood pressure abnormal

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Aphasia	v.24.1	
Blue toe syndrome	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Brain oedema	v.24.1	
Hypersomnia	v.24.1	
Hypoaesthesia	v.24.1	
Hypoaesthesia	v.24.1	
Inflammation	v.24.1	
Loss of consciousness	v.24.1	
Pain in extremity	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:07:47 AM
Initial Received Date:	2021-06-16 to 2021-07-30
Latest Received Date:	N/A
Total Number of Reports:	802 Report(s)

Report Information

***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04471840	2	2021-07-27	2021-09-14	MAH	2021901560	Spontaneous	Pharmacist

Serious report?	Death:	Yes	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
69 Years	Male			Fatal

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cerebrovascular accident	v.24.1	
Deep vein thrombosis	v.24.1	
Immune thrombocytopenia	v.24.1	
Multiple organ dysfunction syndrome	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04471842	0	2021-07-27	2021-07-27	MAH	2021882114	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
44 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
IBUPROFEN	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Chills	v.24.1	
Decreased appetite	v.24.1	
Dizziness	v.24.1	
Headache	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Inappropriate schedule of product administration	v.24.1	
Insomnia	v.24.1	
Muscle spasms	v.24.1	
Myalgia	v.24.1	
Pyrexia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:07:47 AM
Initial Received Date:	2021-06-16 to 2021-07-30
Latest Received Date:	N/A
Total Number of Reports:	802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04471845	0	2021-07-27	2021-07-27	MAH	2021887369	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
76 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ATENOLOL	Concomitant	Tablets	Oral				Heart rate
INDAPAMIDE	Concomitant	Tablets	Oral				Diuretic therapy
LEVOTHYROXINE [LEVOTHYROXINE SODIUM]	Concomitant		Oral				Autoimmune thyroiditis
LIXIANA	Concomitant	Tablets	Oral				Coagulopathy
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
VALSARTAN	Concomitant	NOT SPECIFIED	Oral				Hypertension

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood thyroid stimulating hormone increased	v.24.1	
Dermatitis	v.24.1	
Herpes zoster	v.24.1	
Post herpetic neuralgia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04471846	0	2021-07-27	2021-07-27	MAH	2021881358	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Gait disturbance	v.24.1	
Pain in extremity	v.24.1	
Peripheral swelling	v.24.1	
Pruritus	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04471847	0	2021-07-27	2021-07-27	MAH	2021887361	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
50 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
RABEPRAZOLE	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Asthenia	v.24.1	
Headache	v.24.1	
Palpitations	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04471851	0	2021-07-27	2021-07-27	MAH	2021880768	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
51 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cardiac flutter	v.24.1	43 Hours

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:07:47 AM
Initial Received Date:	2021-06-16 to 2021-07-30
Latest Received Date:	N/A
Total Number of Reports:	802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04471854	0	2021-07-27	2021-07-27	MAH	2021886224	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
41 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.24.1	
Ear pain	v.24.1	0
Enzyme level increased	v.24.1	
Excessive cerumen production	v.24.1	
Head discomfort	v.24.1	
Oropharyngeal pain	v.24.1	0

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pulmonary thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04471858	0	2021-07-27	2021-07-27	MAH	2021901325	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
40 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
VITAMINS NOS	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.24.1	
Migraine	v.24.1	
Musculoskeletal stiffness	v.24.1	
Nausea	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04471860	0	2021-07-27	2021-07-27	MAH	2021887843	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
34 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abortion spontaneous	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04471863	0	2021-07-27	2021-07-27	MAH	2021881359	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
68 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Back pain	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Musculoskeletal stiffness	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04472293	1	2021-07-27	2021-09-08	MAH	2021665530	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
33 Years	Female		93 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
INFLIXIMAB-DYYB	Concomitant		Intravenous (not otherwise specified)	1000.0 Milligram			Colitis ulcerative
MEZAVANT ALSO KNOWN AS MESALAMINE	Concomitant	TABLET (DELAYED AND EXTENDED RELEASE)					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation
PREDNISONE	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Condition aggravated	v.24.1	
Rash	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04473165	0	2021-07-27	2021-07-27	MAH	MOD-2021-265978	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
23 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	Injection		1.0 Dosage forms			COVID-19 immunisation
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Unknown	1.0 Dosage forms			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Lymphadenopathy	v.24.1	48 Hours
Myalgia	v.24.1	48 Hours

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pyrexia	v.24.1	48 Hours
Syncope	v.24.1	
Vaccination site haemorrhage	v.24.1	48 Hours
Vaccination site pain	v.24.1	48 Hours

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04473679	0	2021-07-27	2021-07-27	MAH	2021901310	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
44 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.24.1	
Headache	v.24.1	
Herpes zoster	v.24.1	
Loss of consciousness	v.24.1	
Syncope	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04473864	0	2021-07-27	2021-07-27	MAH	MOD-2021-265849	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
23 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	1.0 Dosage forms			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cold sweat	v.24.1	
Pyrexia	v.24.1	
Seizure	v.24.1	5 Minutes

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04475091	1	2021-07-27	2021-07-29	MAH	2021656732	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
44 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
VISANNE	Suspect	Tablets	Unknown				Endometriosis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Heavy menstrual bleeding	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04475665	0	2021-07-28	2021-07-28	MAH	MOD-2021-264238	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	1.0 Dosage forms			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pericarditis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04477215	0	2021-07-28	2021-07-28	MAH	MOD-2021-264267	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
67 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	1.0 Dosage forms			COVID-19 immunisation
INFLIXIMAB	Suspect	Injection	Intravenous (not otherwise specified)	500.0 Milligram			Crohn's disease
INFLIXIMAB	Suspect		Intravenous (not otherwise specified)	500.0 Milligram			Crohn's disease
INFLIXIMAB	Suspect	Injection	Intravenous (not otherwise specified)	500.0 Milligram			Crohn's disease

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.24.1	
Fatigue	v.24.1	
Pneumonia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04478314	1	2021-07-28	2021-08-12	MAH	2021893541	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
24 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular			1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cognitive disorder	v.24.1	
Feeling abnormal	v.24.1	
Headache	v.24.1	
Hypoaesthesia	v.24.1	
Migraine	v.24.1	
Nausea	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pain	v.24.1	
Palpitations	v.24.1	
Stress	v.24.1	
Thrombosis	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04478656	0	2021-07-28	2021-07-28	MAH	2021868491	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
43 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bell's palsy	v.24.1	
Facial paralysis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04478657	1	2021-07-28	2021-08-11	MAH	2021648815	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
24 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Acne	v.24.1	
Anaphylactic reaction	v.24.1	
Blister	v.24.1	
Bullous impetigo	v.24.1	
Dermatitis contact	v.24.1	
Dry skin	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Erythema	v.24.1	
Eye irritation	v.24.1	
Eye pain	v.24.1	
Herpes simplex	v.24.1	
Ocular hyperaemia	v.24.1	
Ophthalmic herpes zoster	v.24.1	
Paraesthesia	v.24.1	
Perioral dermatitis	v.24.1	
Periorbital disorder	v.24.1	
Photosensitivity reaction	v.24.1	
Rosacea	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04478673	1	2021-07-28	2021-09-06	MAH	2021893525	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Diarrhoea	v.24.1	
Headache	v.24.1	
Pyrexia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04478675	1	2021-07-28	2021-09-14	MAH	202100909997	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
62 Years	Male			Recovered/resolved with sequelae

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown			1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood pressure increased	v.24.1	
Tachycardia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04478681	0	2021-07-28	2021-07-28	MAH	2021893466	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
65 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown			1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Bronchial secretion retention	v.24.1	
Cough	v.24.1	
Fungal infection	v.24.1	
Headache	v.24.1	
Herpes virus infection	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Lethargy	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04478688	1	2021-07-28	2021-08-16	MAH	2021891662	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
42 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood pressure decreased	v.24.1	
Infectious mononucleosis	v.24.1	2167 Hours

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04478689	1	2021-07-28	2021-09-07	MAH	2021894623	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
37 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anxiety	v.24.1	
Dizziness	v.24.1	
Heart rate increased	v.24.1	
Hypertension	v.24.1	
Panic attack	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04478694	2	2021-07-28	2021-09-14	MAH	2021893584	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
38 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Back pain	v.24.1	12 Days
Gait disturbance	v.24.1	
Movement disorder	v.24.1	
Sitting disability	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04478695	0	2021-07-28	2021-07-28	MAH	202100917422	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
33 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Erythema	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Pruritus	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04478722	0	2021-07-28	2021-07-28	MAH	2021895338	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
47 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Inappropriate schedule of product administration	v.24.1	
Migraine	v.24.1	
Off label use	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04478793	2	2021-07-28	2021-09-13	MAH	2021907596	Spontaneous	Physician

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
65 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
HYDROCHLOROTHIAZIDE	Concomitant	Tablets	Oral				Hypertension
OLMESARTAN	Concomitant		Oral				Hypertension
OMEPRAZOLE MAGNESIUM	Concomitant		Oral				Gastrooesophageal reflux disease
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Herpes zoster	v.24.1	
Pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04478800	0	2021-07-28	2021-07-28	MAH	2021899883	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
71 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Diarrhoea	v.24.1	
Dizziness	v.24.1	
Malaise	v.24.1	
Oxygen saturation decreased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04478804	0	2021-07-28	2021-07-28	MAH	2021891822	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
30 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MINERALS NOS/VITAMINS NOS	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Mastitis	v.24.1	0
Off label use	v.24.1	
Product use issue	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04481380	0	2021-07-28	2021-07-28	MAH	2021A600761	Study	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Product used for unknown indication
CALQUENCE	Suspect	Capsules	Oral	100.0 Milligram	1 every 12 Hours		Chronic lymphocytic leukaemia
CALQUENCE	Suspect	Capsules	Oral	100.0 Milligram	1 every 12 Hours	24.0 Days	Chronic lymphocytic leukaemia
CEPHALEXIN	Concomitant	NOT SPECIFIED	Unknown				
IMODIUM	Concomitant	NOT SPECIFIED	Unknown				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal discomfort	v.24.1	
Diarrhoea	v.24.1	
Illness	v.24.1	
Injection site infection	v.24.1	
Localised infection	v.24.1	
Nausea	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04483492	0	2021-07-29	2021-07-29	MAH	ALN-2021-001736	Study	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
40 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect						COVID-19 immunisation
GIVLAARI	Suspect	NOT SPECIFIED	Subcutaneous	2.5 mg/kg			Porphyria acute
IRON	Concomitant						Product used for unknown indication
LIFITEGRAST	Concomitant						Product used for unknown indication
PIMECROLIMUS	Concomitant						Product used for unknown indication

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
VITAMIN D	Concomitant	Capsules					Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pain in extremity	v.24.1	
Platelet count decreased	v.24.1	
Porphyria acute	v.24.1	
Porphyria acute	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04484192	0	2021-07-29	2021-07-29	MAH	MOD-2021-264085	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	1.0 Dosage forms			COVID-19 immunisation
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	Injection	Unknown	1.0 Dosage forms			COVID-19 immunisation
INFLIXIMAB	Suspect		Intravenous (not otherwise specified)	500.0 Milligram			Crohn's disease

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Faecal volume increased	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Porphyria acute	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:07:47 AM
Initial Received Date:	2021-06-16 to 2021-07-30
Latest Received Date:	N/A
Total Number of Reports:	802 Report(s)

Report Information

***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04486126	2	2021-07-29	2021-08-26	MAH	2021BI01033245	Study	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				COVID-19 prophylaxis
TYSABRI	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	300.0 Milligram	1 every 4 Weeks		Relapsing-remitting multiple sclerosis
TYSABRI	Suspect	Unknown	Intravenous (not otherwise specified)	300.0 Milligram	1 every 4 Weeks		Relapsing-remitting multiple sclerosis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Crohn's disease	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Diarrhoea	v.24.1	
Multiple sclerosis relapse	v.24.1	
Vaccination complication	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04486867	1	2021-07-29	2021-09-01	MAH	202100917589	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
28 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bell's palsy	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04487020	1	2021-07-29	2021-09-13	MAH	2021907388	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
12 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	
Pollakiuria	v.24.1	
Thirst	v.24.1	
Type 1 diabetes mellitus	v.24.1	
Weight decreased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04487037	1	2021-07-29	2021-09-01	MAH	202100917386	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
17 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BIPHENTIN	Concomitant	CAPSULE, EXTENDED RELEASE	Oral				Attention deficit hyperactivity disorder
CELEXA [CELECOXIB]	Concomitant		Oral				Anxiety
CITALOPRAM	Concomitant		Oral	30.0 Milligram	1 every 1 Days		
ETHINYL ESTRADIOL/LEVONORGESTREL	Concomitant		Oral				Contraception
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
RITALIN	Concomitant	NOT SPECIFIED	Oral	40.0 Milligram	1 every 1 Days		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Eczema	v.24.1	
Erythema	v.24.1	
Feeling hot	v.24.1	
Pruritus	v.24.1	
Rash papulosquamous	v.24.1	
Skin exfoliation	v.24.1	
Swelling	v.24.1	
Urticaria	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04487087	1	2021-07-29	2021-09-14	MAH	2021907670	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
21 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Myasthenia gravis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:07:47 AM
Initial Received Date:	2021-06-16 to 2021-07-30
Latest Received Date:	N/A
Total Number of Reports:	802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04487273	1	2021-07-29	2021-08-31	MAH	202100923666	Spontaneous	Consumer/other non health professional

Serious report?	Death:	Yes	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
65 Years	Male			Fatal

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Acute leukaemia	v.24.1	
Cerebral haemorrhage	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04487480	0	2021-07-29	2021-07-29	MAH	2021906142	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
63 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
FOLIC ACID	Concomitant	NOT SPECIFIED	Unknown				
HUMIRA	Concomitant	SOLUTION SUBCUTANEOUS	Unknown				
METHOTREXATE	Concomitant	NOT SPECIFIED	Unknown				
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
SYNTHROID	Concomitant	NOT SPECIFIED	Unknown				
VITAMINS NOS	Concomitant		Unknown				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypersensitivity	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pruritus	v.24.1	
Rash	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04488357	0	2021-07-29	2021-07-29	MAH	2021900943	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
RITUXIMAB	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Autoimmune disorder	v.24.1	
Illness	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04489610	0	2021-07-29	2021-07-29	MAH	2021664408	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
50 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
FORMOTEROL FUMARATE/MOMETASONE FUROATE	Concomitant						
MONTELUKAST	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04489614	1	2021-07-29	2021-08-09	MAH	202100962391	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	
Linked	E2B_04606627

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CIMZIA	Concomitant	Solution for injection	Transplacental		Cyclical		Polyarthritis
FOLIC ACID	Concomitant	NOT SPECIFIED	Transplacental		every 1 Days		Pregnancy
HYDROXYCHLOROQUINE SULFATE	Concomitant		Transplacental		every 1 Days		Polyarthritis
IRON	Concomitant		Transplacental		every 1 Days		Pregnancy
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Transplacental		Total	1.0 Days	COVID-19 immunisation
VITAMIN C [ASCORBIC ACID]	Concomitant		Transplacental		every 1 Days		Pregnancy

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
VITAMIN D [COLECALCIFEROL]	Concomitant		Transplacental		1 every 1 Weeks		Pregnancy

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Foetal growth restriction	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Maternal exposure during pregnancy	v.24.1	
Vasodilatation	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:07:47 AM
Initial Received Date:	2021-06-16 to 2021-07-30
Latest Received Date:	N/A
Total Number of Reports:	802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04489656	1	2021-07-29	2021-09-14	MAH	202100909917	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
53 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arrhythmia	v.24.1	
Temperature intolerance	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04491976	0	2021-07-30	2021-07-30	MAH	MOD-2021-238910	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
73 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	1.0 Dosage forms			COVID-19 immunisation
LEVOTHYROXINE SODIUM	Concomitant	NOT SPECIFIED	Unknown		1 every 1 Days		Thyroid disorder
OMEPRAZOLE	Concomitant	NOT SPECIFIED	Unknown	20.0 Milligram	1 every 1 Days		Gastrooesophageal reflux disease
ROSUVASTATIN	Concomitant	NOT SPECIFIED		100.0 Milligram	1 every 1 Days		Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Heart rate increased	v.24.1	
Ventricular tachycardia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04492693	0	2021-07-30	2021-07-30	MAH	2021A616163	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
39 Years	Female		47 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ALPHA-CAROTENE/BETA-CAROTENE/CALCIUM/IRON/VITAMIN C	Concomitant						
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				COVID-19 immunisation
MRNA-1273 SARS-COV-2	Suspect	NOT SPECIFIED					COVID-19 immunisation
TYLENOL	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Chills	v.24.1	
Fatigue	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Malaise	v.24.1	
Maternal exposure during pregnancy	v.24.1	
Off label use	v.24.1	
Pain in extremity	v.24.1	
Placenta praevia	v.24.1	
Premature delivery	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:07:47 AM
Initial Received Date:	2021-06-16 to 2021-07-30
Latest Received Date:	N/A
Total Number of Reports:	802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04493116	1	2021-07-30	2021-08-16	MAH	202100908609	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
47 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Balance disorder	v.24.1	5 Days
Fatigue	v.24.1	5 Days
Gait inability	v.24.1	5 Days
Vertigo	v.24.1	5 Days
Vomiting	v.24.1	5 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04493446	1	2021-07-30	2021-09-14	MAH	2021901155	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
51 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest discomfort	v.24.1	
Dyspnoea exertional	v.24.1	
Palpitations	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04493452	1	2021-07-30	2021-09-13	MAH	2021907755	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
43 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blister	v.24.1	
Condition aggravated	v.24.1	
Feeling hot	v.24.1	
Inflammation	v.24.1	
Lethargy	v.24.1	
Pain	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pain	v.24.1	
Rash pruritic	v.24.1	
Swelling	v.24.1	
Vaccination site pruritus	v.24.1	
Vaccination site rash	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04493709	0	2021-07-30	2021-07-30	MAH	2021908467	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
36 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BETA-CAROTENE/BIOFLAVONOIDS/BIOTIN/CALCIUM ASCORBATE/CALCIUM D-PANTOTHENATE/CALCIUM PHOSPHATE/CHOLINE BITARTRATE/CHROMIC CHLORIDE/COPPER SULFATE/DL-ALPHA TOCOPHERYL ACID SUCCINATE/FOLIC ACID/HESPERIDIN/INOSITOL/IRON AMINO ACID CHELATE	Concomitant						
IRON	Concomitant						

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
VITAMIN D	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Eye inflammation	v.24.1	
Eye injury	v.24.1	
Eye swelling	v.24.1	
Headache	v.24.1	
Seasonal allergy	v.24.1	
Vasodilatation	v.24.1	
Vision blurred	v.24.1	
Visual impairment	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04494261	0	2021-07-30	2021-07-30	MAH	2021523415	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
67 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CALCIUM CARBONATE/VITAMIN D3	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
VITAMIN D	Concomitant		Oral				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.24.1	1 Days
Lymphadenopathy	v.24.1	170 Hours
Nausea	v.24.1	170 Hours

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Vaccination site pain	v.24.1	170 Hours

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:07:47 AM
Initial Received Date: 2021-06-16 to 2021-07-30
Latest Received Date: N/A
Total Number of Reports: 802 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04494413	0	2021-07-30	2021-07-30	MAH	21K-028-4013170-00	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
65 Years	Male		67 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular			0.0	COVID-19 prophylaxis
HUMIRA	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous				Product used for unknown indication
HYDROCORTISONE	Concomitant	NOT SPECIFIED	Intravenous (not otherwise specified)	100.0 Milligram			Product used for unknown indication
IMURAN	Suspect	NOT SPECIFIED	Unknown				Product used for unknown indication
INFLIXIMAB	Suspect	NOT SPECIFIED	Intravenous (not otherwise specified)	400.0 Milligram		-143.0	Crohn's disease

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
INFLIXIMAB	Suspect	Powder for injection	Intravenous (not otherwise specified)	10.0 mg/kg	1 every 6 Weeks		Crohn's disease
INFLIXIMAB	Suspect	Powder for injection	Intravenous (not otherwise specified)	400.0 Milligram		-159.0	Crohn's disease
METHOTREXATE	Suspect	NOT SPECIFIED	Unknown				Product used for unknown indication
NIFEDIPINE	Concomitant						Product used for unknown indication
PANTOPRAZOLE	Concomitant	NOT SPECIFIED					Product used for unknown indication
PENTASA	Concomitant	NOT SPECIFIED					Product used for unknown indication
POTASSIUM	Concomitant	NOT SPECIFIED					Product used for unknown indication
PREDNISONE	Concomitant	NOT SPECIFIED					Product used for unknown indication
REMICADE	Suspect	POWDER FOR SOLUTION INTRAVENOUS	Unknown				Product used for unknown indication
TYLENOL	Concomitant	NOT SPECIFIED	Oral	650.0 Milligram		1.0 Days	Product used for unknown indication
VITAMIN B12	Concomitant	NOT SPECIFIED					Product used for unknown indication
VITAMIN D	Concomitant	Capsules					Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest discomfort	v.24.1	
Chest pain	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.24.1	
Crohn's disease	v.24.1	
Drug hypersensitivity	v.24.1	
Drug hypersensitivity	v.24.1	
Drug hypersensitivity	v.24.1	
Drug hypersensitivity	v.24.1	
Fibrin D dimer increased	v.24.1	
Hypoaesthesia	v.24.1	
Livedo reticularis	v.24.1	
Muscle spasms	v.24.1	
Paraesthesia	v.24.1	
Peripheral coldness	v.24.1	
Peripheral embolism	v.24.1	
Pruritus	v.24.1	1 Days
Pulmonary embolism	v.24.1	
Rash	v.24.1	1 Days
Somnolence	v.24.1	
Thrombosis	v.24.1	

Health Canada Santé Canada

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:08:27 AM
Initial Received Date:	2021-07-30 to 2021-09-30
Latest Received Date:	N/A
Total Number of Reports:	703 Report(s)

Brand Name/Active Ingredient: covid
Search Date Criteria: 2021-07-30 to 2021-09-30
Reaction Term(s): All/Tous
Serious report?: Both
Type of Report: All
Source of Report: All
Gender: All
Report Outcome: All
Age: All

CAVEAT: This summary is based on information from adverse reaction reports submitted by health professionals and laypersons either directly to Health Canada or via market authorization holders. Each report represents the suspicion, opinion or observation of the individual reporter. The Canada Vigilance Program is a spontaneous reporting system that is suitable to detect signals of potential health product safety issues during the post-market period. The data has been collected primarily by a spontaneous surveillance system in which adverse reactions to health products are reported on a voluntary basis. Under reporting of adverse reactions is seen with both voluntary and mandatory spontaneous surveillance systems. Accumulated case reports should not be used as a basis for determining the incidence of a reaction or estimating risk for a particular product as neither the total number of reactions occurring, nor the number of patients exposed to the health product is known. Because of the multiple factors that influence reporting, quantitative comparisons of health product safety cannot be made from the data. Some of these factors include the length of time a drug is marketed, the market share, size and sophistication of the sales force, publicity about an adverse reaction and regulatory actions. In some cases, the reported clinical data is incomplete and there is not certainty that these health products caused the reported reactions. A given reaction may be due to an underlying disease process or to another coincidental factor. This information is provided with the understanding that the data will be appropriately referenced and used in conjunction with this caveat statement.

Canada

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information

***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000961137	0	2021-07-30	2021-07-30	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
48 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Ear pain	v.24.1	82 Days
Hypoaesthesia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000961287	0	2021-07-31	2021-07-31	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
24 Years	Female	165 Centimeter	45 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood pressure fluctuation	v.24.1	
Dyspepsia	v.24.1	
Dyspnoea	v.24.1	
Fatigue	v.24.1	
Feeling abnormal	v.24.1	
Feeling hot	v.24.1	
Head discomfort	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.24.1	
Heart rate increased	v.24.1	
Hypoaesthesia	v.24.1	
Limb discomfort	v.24.1	
Nausea	v.24.1	
Palpitations	v.24.1	
Paraesthesia	v.24.1	
Paralysis	v.24.1	
Peripheral coldness	v.24.1	
Presyncope	v.24.1	
Thirst	v.24.1	
Tremor	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000961288	0	2021-07-31	2021-07-31	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
35 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR				30.0 Days	
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Irritability	v.24.1	
Menstruation delayed	v.24.1	
Mood altered	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000961289	0	2021-07-30	2021-07-30	Hospital		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
30 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.24.1	
Nausea	v.24.1	
Pericarditis	v.24.1	
Pyrexia	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000961290	0	2021-07-30	2021-07-30	Hospital		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
78 Years	Female	163 Centimeter	87 Kilogram	Recovering/resolving

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID VACCINE	Suspect	SOLUTION INTRAMUSCULAR	Subcutaneous		Once		
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Subcutaneous		Once		
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Subcutaneous				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bronchospasm	v.24.1	3 Days
Oedema peripheral	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000961291	0	2021-07-30	2021-07-30	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
43 Years	Female	173 Centimeter	79 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dysmenorrhoea	v.24.1	
Heavy menstrual bleeding	v.24.1	
Menstruation delayed	v.24.1	
Menstruation irregular	v.24.1	7 Days
Polymenorrhoea	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:08:27 AM
Initial Received Date:	2021-07-30 to 2021-09-30
Latest Received Date:	N/A
Total Number of Reports:	703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000961292	0	2021-07-30	2021-07-30	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
58 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR		1.0 Dosage forms			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest discomfort	v.24.1	
Dyspnoea	v.24.1	
Pericardial effusion	v.24.1	
Pericarditis	v.24.1	
Tachycardia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000961296	0	2021-07-30	2021-07-30	Hospital		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
22 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000961297	0	2021-07-30	2021-07-30	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
20 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.24.1	
Chills	v.24.1	
Myocarditis	v.24.1	
Pericarditis	v.24.1	
Pyrexia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000961300	0	2021-07-30	2021-07-30	Hospital		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
70 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Aphasia	v.24.1	
Facial paralysis	v.24.1	
Urinary incontinence	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000961301	0	2021-07-30	2021-07-30	Community		Spontaneous	Physician

Serious report?	Death:		Disability:		Congenital Anomaly:	
Not Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
53 Years	Female	65 Inch	154 Pound	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	0.5 ml	Once	13.0 Days	COVID-19 immunisation
SYNTHROID	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Urticaria	v.24.1	13 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000961302	0	2021-07-30	2021-07-30	Community		Spontaneous	Other health professional

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:	Yes	Hospitalization:	Yes	Other Medically Important Conditions:	

Patient Information

Age	Gender	Height	Weight	Report Outcome
45 Years	Female	64 Inch	154 Pound	Recovering/resolving

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Subcutaneous		1 every 1 Days		Visual impairment

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Vision blurred	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000961303	0	2021-08-02	2021-08-02	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
24 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Rash erythematous	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000961305	0	2021-07-30	2021-07-30	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR				73.0 Days	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood glucose decreased	v.24.1	
Decreased insulin requirement	v.24.1	
Pre-existing condition improved	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000961307	0	2021-08-01	2021-08-01	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
22 Years	Male	69 Inch		Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Once		COVID-19 prophylaxis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cold sweat	v.24.1	
Dizziness	v.24.1	
Presyncope	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000961308	0	2021-08-02	2021-08-02	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
38 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Peripheral swelling	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000961317	0	2021-07-31	2021-07-31	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
26 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR			Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fear	v.24.1	
Impaired work ability	v.24.1	
Mobility decreased	v.24.1	
Pain	v.24.1	
Pain in extremity	v.24.1	
Superficial vein thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000961472	0	2021-08-03	2021-08-03	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
68 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ANTI-HYPERTENSIVE MEDICATION(S)	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				COVID-19 immunisation
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR					COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Diarrhoea	v.24.1	
Diarrhoea haemorrhagic	v.24.1	
Feeding disorder	v.24.1	
Palpitations	v.24.1	
Tremor	v.24.1	
Vision blurred	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000961473	0	2021-08-03	2021-08-03	Community		Spontaneous	Physician

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
75 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
HYDROCHLOROTHIAZIDE	Concomitant	Tablets					
MAVIK	Concomitant	Capsules					
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular		Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Gout	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000961694	0	2021-08-04	2021-08-04	Hospital		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
35 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Once		Immunisation
SERTRALINE	Concomitant	Capsules					
TRAZODONE	Concomitant	Tablets					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Dizziness	v.24.1	
Eye irritation	v.24.1	
Gait disturbance	v.24.1	
Headache	v.24.1	
Ocular discomfort	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Visual impairment	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000961695	0	2021-08-04	2021-08-04	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
36 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		COVID-19 immunisation
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Malaise	v.24.1	
Pain in extremity	v.24.1	
Seizure	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000961699	0	2021-08-04	2021-08-04	Hospital		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
55 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AMLODIPINE	Concomitant	Tablets	Unknown				
ATORVASTATIN	Concomitant	NOT SPECIFIED	Unknown				
BISOPROLOL	Concomitant	Tablets	Unknown				
CANDESARTAN	Concomitant						
CLOPIDOGREL	Concomitant	Tablets					
HYDRALAZINE	Concomitant	NOT SPECIFIED					
MELATONIN	Concomitant	NOT SPECIFIED					
PANTOPRAZOLE	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		Immunisation
POTASSIUM (NOS)	Concomitant	NOT SPECIFIED					
SPIRONOLACTONE	Concomitant	Tablets					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Aphasia	v.24.1	
Dysarthria	v.24.1	
Eye disorder	v.24.1	
Facial paralysis	v.24.1	
Muscular weakness	v.24.1	
Pain in extremity	v.24.1	
Tongue paralysis	v.24.1	
Vision blurred	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000961881	0	2021-08-05	2021-08-05	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID VACCINE	Suspect	SOLUTION INTRAMUSCULAR					
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood cholesterol increased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000961882	0	2021-08-05	2021-08-05	Community		Spontaneous	Nurse

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
24 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypoaesthesia	v.24.1	
Muscular weakness	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000961883	0	2021-08-05	2021-08-05	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
70 Years	Female	160 Centimeter	108 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASA	Concomitant	NOT SPECIFIED					
DEPO-MEDROL	Concomitant	SUSPENSION INTRA-ARTICULAR					
LISINOPRIL	Concomitant	Tablets					
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular		Once		
TIMOLOL	Concomitant	NOT SPECIFIED					
ZOVIRAX	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Vertigo	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000961885	0	2021-08-05	2021-08-05	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Parenteral				COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cerebrovascular accident	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000961886	0	2021-08-05	2021-08-05	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
42 Years	Female	84 Inch	215 Pound	Recovered/resolved with sequelae

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain	v.24.1	
Diarrhoea	v.24.1	
Nausea	v.24.1	
Rhinorrhoea	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000961898	0	2021-08-06	2021-08-06	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:		Disability:	Yes	Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:	Yes	Other Medically Important Conditions:	

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR					COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Disability	v.24.1	
Hospitalisation	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000962089	0	2021-08-06	2021-08-06	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
61 Years	Male			Recovered/resolved with sequelae

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID VACCINE	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular		Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arterial rupture	v.24.1	
Blindness	v.24.1	
Cerebrovascular accident	v.24.1	
Haemorrhagic stroke	v.24.1	
Insomnia	v.24.1	
Memory impairment	v.24.1	
Speech disorder	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000962090	0	2021-08-06	2021-08-06	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
13 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dysuria	v.24.1	
Genital discolouration	v.24.1	
Headache	v.24.1	
Pyrexia	v.24.1	
Vaccination site pain	v.24.1	
Vaginal ulceration	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Vulvovaginal pain	v.24.1	
Vulvovaginal pruritus	v.24.1	
Vulvovaginal swelling	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000962092	0	2021-08-06	2021-08-06	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
50 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Angina pectoris	v.24.1	
Chest discomfort	v.24.1	
Heart rate abnormal	v.24.1	
Insomnia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000962098	0	2021-08-07	2021-08-07	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
36 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pruritus	v.24.1	
Urticaria	v.24.1	7 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000962100	0	2021-08-07	2021-08-07	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
43 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Bone pain	v.24.1	
Chest pain	v.24.1	
Diarrhoea	v.24.1	
Dyspnoea	v.24.1	
Fatigue	v.24.1	
Head discomfort	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.24.1	
Heart rate decreased	v.24.1	
Hypoaesthesia	v.24.1	
Inflammation	v.24.1	
Loss of consciousness	v.24.1	
Mental impairment	v.24.1	
Muscle discomfort	v.24.1	
Myalgia	v.24.1	
Ocular discomfort	v.24.1	
Pulmonary pain	v.24.1	
Visual impairment	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000962101	0	2021-08-07	2021-08-07	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
58 Years	Female	165 Centimeter	164 Pound	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Bedridden	v.24.1	
Eye disorder	v.24.1	
Facial pain	v.24.1	
Headache	v.24.1	
Hypoaesthesia	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Myalgia	v.24.1	
Pain in jaw	v.24.1	
Peripheral swelling	v.24.1	
Swelling face	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000962102	0	2021-08-06	2021-08-06	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
36 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					
SCOPOLAMINE HYDROBROMIDE INJECTION	Concomitant	LIQUID					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Motion sickness	v.24.1	9 Days
Rash	v.24.1	9 Days
Urticaria	v.24.1	9 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000962104	0	2021-08-06	2021-08-06	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
61 Years	Male	74 Inch	250 Pound	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Parenteral			81.0 Days	COVID-19
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					COVID-19

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Hypoaesthesia	v.24.1	
Neck pain	v.24.1	
Neuralgic amyotrophy	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000962107	0	2021-08-08	2021-08-08	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Menstrual disorder	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000962108	0	2021-08-08	2021-08-08	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Back pain	v.24.1	
Fatigue	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000962110	0	2021-08-06	2021-08-06	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bedridden	v.24.1	
Chills	v.24.1	
Malaise	v.24.1	
Nausea	v.24.1	
Pyrexia	v.24.1	
Swelling face	v.24.1	
Vaccination complication	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000962294	0	2021-08-09	2021-08-09	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
37 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				COVID-19 prophylaxis
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				COVID-19 prophylaxis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal distension	v.24.1	
Dysmenorrhoea	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	
Heavy menstrual bleeding	v.24.1	
Impaired work ability	v.24.1	
Menstrual disorder	v.24.1	
Polymenorrhoea	v.24.1	62 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000962296	0	2021-08-09	2021-08-09	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
52 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVERSYL	Concomitant	Tablets					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml		48.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000962297	0	2021-08-09	2021-08-09	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
46 Years	Female	154 Centimeter	60 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR					COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Amenorrhoea	v.24.1	
Pollakiuria	v.24.1	
Vaginal discharge	v.24.1	
Vitreous floaters	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000962298	0	2021-08-09	2021-08-09	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
51 Years	Male	188 Centimeter	90 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Ageusia	v.24.1	
Bell's palsy	v.24.1	50 Days
Eyelid function disorder	v.24.1	
Facial paralysis	v.24.1	
Speech disorder	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000962570	0	2021-08-10	2021-08-10	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
22 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
HYDROCORTISONE ACETATE CREAM USP	Concomitant	Cream					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR			Once		
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anovulatory cycle	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000962571	0	2021-08-10	2021-08-10	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
61 Years	Female	163 Centimeter	74 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BENADRYL	Concomitant	Capsules					
CETIRIZINE	Concomitant	Tablets					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Urticaria	v.24.1	8 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000962783	0	2021-08-11	2021-08-11	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
13 Years	Female	163 Centimeter	50 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Duplicate	000963015

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fall	v.24.1	
Loss of consciousness	v.24.1	2 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:08:27 AM
Initial Received Date:	2021-07-30 to 2021-09-30
Latest Received Date:	N/A
Total Number of Reports:	703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000962784	0	2021-08-11	2021-08-11	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
38 Years				Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR			Once		
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR			Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Gait disturbance	v.24.1	
Hypoaesthesia	v.24.1	
Pain in extremity	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000962788	0	2021-08-11	2021-08-11	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
46 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Rash	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:08:27 AM
Initial Received Date:	2021-07-30 to 2021-09-30
Latest Received Date:	N/A
Total Number of Reports:	703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000963007	0	2021-08-13	2021-08-13	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
49 Years	Female	165 Centimeter	180 Pound	Recovering/resolving

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CARBAMAZEPINE	Concomitant	NOT SPECIFIED					
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	1.0 Dosage forms	Once		COVID-19

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Loss of consciousness	v.24.1	
Seizure	v.24.1	
Vertigo	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000963009	0	2021-08-12	2021-08-12	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
57 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect			0.5 ml	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Rash erythematous	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000963012	0	2021-08-12	2021-08-12	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
42 Years				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pain	v.24.1	
Thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000963015	1	2021-08-12	2021-08-24	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
13 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Duplicate	000962783

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fall	v.24.1	
Loss of consciousness	v.24.1	
Syncope	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000963198	0	2021-08-13	2021-08-13	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
26 Years	Female	165 Centimeter	58 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ADVIL	Concomitant	NOT SPECIFIED					
BUPROPION	Concomitant	Tablets					
FLUOXETINE	Concomitant	NOT SPECIFIED					
FOQUEST	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Heavy menstrual bleeding	v.24.1	
Menstrual disorder	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000963199	0	2021-08-14	2021-08-14	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
37 Years	Male	179 Centimeter	199 Pound	Recovering/resolving

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Subcutaneous		Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Back pain	v.24.1	
Fatigue	v.24.1	
Haemorrhage subcutaneous	v.24.1	
Tremor	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000963203	0	2021-08-15	2021-08-15	Hospital		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
36 Years	Male	178 Centimeter	84 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Subcutaneous				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Autonomic nervous system imbalance	v.24.1	
General physical health deterioration	v.24.1	
Guillain-Barre syndrome	v.24.1	
Hyporeflexia	v.24.1	
Myalgia	v.24.1	
Paraesthesia	v.24.1	
Pyrexia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000963204	0	2021-08-13	2021-08-13	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
21 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular		Once	33.0 Days	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.24.1	
Headache	v.24.1	
Mass	v.24.1	
Pain in extremity	v.24.1	
Skin discolouration	v.24.1	
Skin disorder	v.24.1	
Thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000963207	0	2021-08-13	2021-08-13	Community		Spontaneous	Physician

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
73 Years	Male	178 Centimeter	81 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ALLOPURINOL	Concomitant	Tablets					
LOSARTAN	Concomitant	Tablets					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR			Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Gingivitis	v.24.1	
Glossitis	v.24.1	
Onycholysis	v.24.1	
Psoriasis	v.24.1	
Skin exfoliation	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000963209	0	2021-08-13	2021-08-13	Community		Spontaneous	Physician

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:	Yes	Hospitalization:	Yes	Other Medically Important Conditions:	

Patient Information

Age	Gender	Height	Weight	Report Outcome
72 Years	Male	72 Inch	80 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR					Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Encephalitis	v.24.1	
Interstitial lung disease	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000963212	0	2021-08-15	2021-08-15	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
43 Years	Female	180 Centimeter	66 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR					COVID-19

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Lymph node pain	v.24.1	
Movement disorder	v.24.1	
Myalgia	v.24.1	
Rheumatic disorder	v.24.1	
Tendon pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000963410	0	2021-08-16	2021-08-16	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
35 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Asthenia	v.24.1	
Dizziness	v.24.1	
Dysmenorrhoea	v.24.1	
Fatigue	v.24.1	
Hypoaesthesia	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Inflammatory marker increased	v.24.1	
Joint stiffness	v.24.1	
Motor dysfunction	v.24.1	
Musculoskeletal stiffness	v.24.1	
Pain	v.24.1	
Paraesthesia	v.24.1	
Photophobia	v.24.1	
Tremor	v.24.1	
Vision blurred	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000963411	0	2021-08-16	2021-08-16	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
29 Years	Female	162 Centimeter	180 Pound	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bell's palsy	v.24.1	
Facial paralysis	v.24.1	
Herpes zoster	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000963628	0	2021-08-17	2021-08-17	Community		Spontaneous	Physician

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
26 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR			Once		COVID-19 prophylaxis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.24.1	
Pericarditis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000963629	0	2021-08-17	2021-08-17	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
75 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect				Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Aphonia	v.24.1	
Cough	v.24.1	
Dry throat	v.24.1	
Oropharyngeal pain	v.24.1	
Throat irritation	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000963630	0	2021-08-17	2021-08-17	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
30 Years	Female	160 Centimeter	57 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Amenorrhoea	v.24.1	
Menstruation delayed	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000963632	1	2021-08-17	2021-08-23	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
39 Years	Female	160 Centimeter	57 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	1.0 Dosage forms	Once		COVID-19 prophylaxis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain upper	v.24.1	
Arthralgia	v.24.1	
Chills	v.24.1	
Diarrhoea	v.24.1	
Dizziness	v.24.1	
Fatigue	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.24.1	
Limb discomfort	v.24.1	
Malaise	v.24.1	3 Days
Myalgia	v.24.1	
Nausea	v.24.1	
Pain	v.24.1	
Pain in extremity	v.24.1	
Pyrexia	v.24.1	
Rash	v.24.1	
Vaccination site erythema	v.24.1	
Vaccination site swelling	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000963633	0	2021-08-17	2021-08-17	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
12 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	30.0 Microgram	Once		Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain upper	v.24.1	
Crying	v.24.1	
Hyperhidrosis	v.24.1	
Nasopharyngitis	v.24.1	
Pallor	v.24.1	
Unresponsive to stimuli	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000963635	0	2021-08-17	2021-08-17	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
28 Years	Female	63 Inch	135 Pound	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular			73.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Heavy menstrual bleeding	v.24.1	42 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000963637	0	2021-08-17	2021-08-17	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
49 Years	Male	183 Centimeter	102 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				COVID-19

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blister	v.24.1	17 Days
Oral herpes	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000963971	0	2021-08-19	2021-08-19	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
30 Years	Female	182 Centimeter	80 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PANTOPRAZOLE MAGNESIUM	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml			COVID-19 prophylaxis
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml			COVID-19 prophylaxis
RIZATRIPTAN ODT	Concomitant	TABLET (ORALLY DISINTEGRATING)					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Herpes zoster	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000963973	0	2021-08-20	2021-08-20	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
19 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Allergy to vaccine	v.24.1	
Cough	v.24.1	
Dermatitis allergic	v.24.1	
Dizziness	v.24.1	
Dyspnoea	v.24.1	
Erythema	v.24.1	
Fatigue	v.24.1	
Inflammation	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Oropharyngeal pain	v.24.1	
Pyrexia	v.24.1	
Rash	v.24.1	
Wheezing	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:08:27 AM
Initial Received Date:	2021-07-30 to 2021-09-30
Latest Received Date:	N/A
Total Number of Reports:	703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000963975	0	2021-08-19	2021-08-19	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
35 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular		Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Latent autoimmune diabetes in adults	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000963977	2	2021-08-19	2021-09-10	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
40 Years	Female	163 Centimeter	200 Pound	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood pressure increased	v.24.1	
Pruritus	v.24.1	
Rash	v.24.1	41 Days
Urticaria	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000964152	0	2021-08-20	2021-08-20	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
35 Years	Female	169 Centimeter	47 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ALESSE 21	Concomitant	Tablets					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					COVID-19

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Heavy menstrual bleeding	v.24.1	
Intermenstrual bleeding	v.24.1	
Menstrual disorder	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:08:27 AM
Initial Received Date:	2021-07-30 to 2021-09-30
Latest Received Date:	N/A
Total Number of Reports:	703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000964154	0	2021-08-22	2021-08-22	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
44 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000964155	1	2021-08-22	2021-12-16	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
59 Years	Male	168 Centimeter	75 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ALFUZOSIN	Concomitant	TABLET (EXTENDED-RELEASE)					
CLONAZEPAM	Concomitant	Tablets					
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intravenous (not otherwise specified)		Once		COVID-19
RAN-CIPROFLOX	Suspect	Tablets	Oral	500.0 Milligram		42.0 Days	Prostatitis
SEREVENT	Concomitant	NOT SPECIFIED					

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
TUDORZA GENUAIR FOR ORAL INHALATION. 1 INHALER WITH 30 ACTUATIONS & 1 INHALER WITH 60 ACTUATIONS	Suspect	POWDER, METERED DOSE					
VENTOLIN	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Balance disorder	v.24.1	
Bedridden	v.24.1	
Bradycardia	v.24.1	95 Days
Depression	v.24.1	
Dizziness	v.24.1	
Prostatitis	v.24.1	
Suicidal ideation	v.24.1	
Vertigo	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000964156	0	2021-08-20	2021-08-20	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
21 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Once		COVID-19 prophylaxis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.24.1	2 Days
Pharyngeal swelling	v.24.1	
Pruritus	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000964159	0	2021-08-20	2021-08-20	Hospital		Spontaneous	Other health professional

Serious report?	Death:	Yes	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
86 Years	Female			Fatal

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ELIQUIS	Suspect	Tablets					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.24.1	
Muscle tightness	v.24.1	
Palliative care	v.24.1	
Subarachnoid haemorrhage	v.24.1	
Unresponsive to stimuli	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000964368	0	2021-08-23	2021-08-23	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
27 Years	Female	64 Inch	220 Pound	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CIPRALEX	Concomitant	Tablets					
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect						COVID-19 immunisation
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR					COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Urticaria	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000964370	0	2021-08-23	2021-08-23	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
49 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Balance disorder	v.24.1	
Vertigo	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000964372	0	2021-08-23	2021-08-23	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
36 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MARVELON 28	Concomitant	Tablets					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml			COVID-19 prophylaxis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.24.1	
Muscle spasms	v.24.1	
Syncope	v.24.1	
Unresponsive to stimuli	v.24.1	
Vaccination site pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000964375	0	2021-08-23	2021-08-23	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
27 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml			Prophylaxis
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml			Prophylaxis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.24.1	
Headache	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Heavy menstrual bleeding	v.24.1	
Insomnia	v.24.1	
Menstruation irregular	v.24.1	
Tinnitus	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000964567	0	2021-08-24	2021-08-24	Community		Spontaneous	Physician

Serious report?	Death:	Disability:	Congenital Anomaly:
Serious	Yes	No	No
	Life Threatening: No	**Hospitalization:** No	**Other Medically Important Conditions:** No

Patient Information

Age	Gender	Height	Weight	Report Outcome
18 Years	Female	160 Centimeter	50 Kilogram	Fatal

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Death	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000964575	0	2021-08-24	2021-08-24	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
75 Years	Male	69 Inch	175 Pound	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	0.5 ml	Once		COVID-19 prophylaxis
NAPROXEN	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Fatigue	v.24.1	
Myalgia	v.24.1	
Somnolence	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:08:27 AM
Initial Received Date:	2021-07-30 to 2021-09-30
Latest Received Date:	N/A
Total Number of Reports:	703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000964577	0	2021-08-24	2021-08-24	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
83 Years	Female	67 Inch	140 Pound	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID 19 VACCINE MODERNA	Suspect		Intramuscular		Once		COVID-19 immunisation
COVID 19 VACCINE MODERNA	Suspect		Intramuscular				COVID-19 immunisation
HYDROCHLOROTHIAZIDE	Concomitant	Tablets					
ROSUVASTATIN	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dry skin	v.24.1	
Rash macular	v.24.1	28 Days
Skin exfoliation	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Swelling	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000964579	0	2021-08-24	2021-08-24	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:		Disability:	Yes	Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	

Patient Information

Age	Gender	Height	Weight	Report Outcome
56 Years	Female	65 Inch	182 Pound	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	000984253

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR			Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Adnexa uteri pain	v.24.1	
Insomnia	v.24.1	
Loss of personal independence in daily activities	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000964581	0	2021-08-24	2021-08-24	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:		Disability:		Congenital Anomaly:	
Not Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
45 Years	Female	57 Inch	166 Pound	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	0.5 ml	Once	56.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain	v.24.1	
Heavy menstrual bleeding	v.24.1	
Menstruation irregular	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000964584	0	2021-08-24	2021-08-24	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
69 Years	Female	66 Inch	148 Pound	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				COVID-19 immunisation
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Erythema	v.24.1	
Fatigue	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hemiparesis	v.24.1	
Loss of personal independence in daily activities	v.24.1	
Lymphadenopathy	v.24.1	
Musculoskeletal stiffness	v.24.1	
Myalgia	v.24.1	
Paraesthesia	v.24.1	
Swelling	v.24.1	
Swelling face	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000964589	0	2021-08-24	2021-08-24	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:		Disability:	Yes	Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	

Patient Information

Age	Gender	Height	Weight	Report Outcome
43 Years	Female	157 Centimeter	100 Pound	Recovering/resolving

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID 19 VACCINE MODERNA	Suspect		Intramuscular	0.5 ml	Once	24.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Loss of personal independence in daily activities	v.24.1	
Muscle injury	v.24.1	
Muscular weakness	v.24.1	
Pain in extremity	v.24.1	
Rhabdomyolysis	v.24.1	
Walking disability	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000964591	0	2021-08-24	2021-08-24	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
75 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR			Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Retinal vascular thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000964593	0	2021-08-24	2021-08-24	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:		Disability:		Congenital Anomaly:	
Not Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
44 Years	Female	68 Inch	200 Pound	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
OZEMPIC	Concomitant	SOLUTION SUBCUTANEOUS					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				COVID-19 immunisation
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dysmenorrhoea	v.24.1	4 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000964599	0	2021-08-24	2021-08-24	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:		Disability:		Congenital Anomaly:	
Not Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
78 Years	Female	65 Inch	161 Pound	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR				59.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Chest pain	v.24.1	5 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000964833	0	2021-08-25	2021-08-25	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Migraine	v.24.1	
Paraesthesia	v.24.1	
Thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000965059	0	2021-08-26	2021-08-26	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
62 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular				COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Shoulder injury related to vaccine administration	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000965060	0	2021-08-26	2021-08-26	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
20 Years	Female	164 Centimeter	72 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID 19 VACCINE MODERNA	Suspect		Intramuscular		Once		COVID-19 immunisation
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.24.1	
Chills	v.24.1	
Fibrin D dimer increased	v.24.1	
Left atrial enlargement	v.24.1	
Lymphadenopathy	v.24.1	
Myalgia	v.24.1	
Pyrexia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000965061	0	2021-08-26	2021-08-26	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
19 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR			Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Intermenstrual bleeding	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000965062	0	2021-08-26	2021-08-26	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:		Disability:		Congenital Anomaly:	
Not Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
46 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR			Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Diarrhoea	v.24.1	
Dyspnoea	v.24.1	
Hypoaesthesia	v.24.1	
Malaise	v.24.1	
Nausea	v.24.1	
Paraesthesia	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Polyneuropathy	v.24.1	
Pruritus	v.24.1	
Throat tightness	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000965063	0	2021-08-26	2021-08-26	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
35 Years	Female	180 Centimeter	65 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Intermenstrual bleeding	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000965066	0	2021-08-26	2021-08-26	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
UNKNOWN COVID VACCINE	Suspect						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000965069	0	2021-08-26	2021-08-26	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
61 Years	Male			Recovering/resolving

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular		Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Macular oedema	v.24.1	
Retinal vein occlusion	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000965071	0	2021-08-26	2021-08-26	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
38 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bell's palsy	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000965257	0	2021-08-29	2021-08-29	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
57 Years	Male	168 Centimeter		Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					COVID-19 immunisation
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Subcutaneous				COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Fatigue	v.24.1	
Muscle tightness	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000965258	0	2021-08-28	2021-08-28	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
37 Years	Female	168 Centimeter		Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		COVID-19 immunisation
VENLAFAXINE HYDROCHLORIDE	Concomitant	CAPSULE, EXTENDED RELEASE					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal discomfort	v.24.1	
Asthenia	v.24.1	
Chills	v.24.1	
Dysstasia	v.24.1	
Faeces soft	v.24.1	
Feeling hot	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hyperhidrosis	v.24.1	
Nasal congestion	v.24.1	
Nasal discomfort	v.24.1	
Nausea	v.24.1	
Pyrexia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000965259	0	2021-08-30	2021-08-30	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
32 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Dizziness	v.24.1	
Heavy menstrual bleeding	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000965260	0	2021-08-28	2021-08-28	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
63 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE	Suspect	SOLUTION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Haematoma muscle	v.24.1	60 Days
Joint range of motion decreased	v.24.1	
Vaccination site pain	v.24.1	
Vaccination site swelling	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000965267	0	2021-08-27	2021-08-27	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
49 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
LAMISIL	Concomitant	NOT SPECIFIED					
MOMETASONE FUROATE	Concomitant	NOT SPECIFIED					
NAPROSYN	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR			Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal discomfort	v.24.1	
Abdominal pain lower	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000965268	0	2021-08-27	2021-08-27	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:		Disability:		Congenital Anomaly:	
Not Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
29 Years	Female	164 Centimeter	58 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular				
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Amenorrhoea	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000965269	0	2021-08-29	2021-08-29	Hospital		Spontaneous	Pharmacist

Serious report?	Death:		Disability:		Congenital Anomaly:	
Not Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
56 Years	Male			Recovering/resolving

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR			Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pericarditis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000965271	0	2021-08-28	2021-08-28	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death: Yes	Disability:	Congenital Anomaly:
Serious	Life Threatening:	Hospitalization:	Other Medically Important Conditions:

Patient Information

Age	Gender	Height	Weight	Report Outcome
25 Years	Male			Fatal

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect				Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cardiac arrest	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000965447	0	2021-08-30	2021-08-30	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
34 Years	Female			Recovering/resolving

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000965448	0	2021-08-30	2021-08-30	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
37 Years	Female	63 Inch	150 Pound	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.24.1	
Dysphagia	v.24.1	
Fatigue	v.24.1	
Lymphadenopathy	v.24.1	
Malaise	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:08:27 AM
Initial Received Date:	2021-07-30 to 2021-09-30
Latest Received Date:	N/A
Total Number of Reports:	703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000965451	0	2021-08-30	2021-08-30	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bell's palsy	v.24.1	
Lymphadenopathy	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000965659	0	2021-08-31	2021-08-31	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
42 Years	Male	180 Centimeter	80 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dyspnoea	v.24.1	87 Days
Fatigue	v.24.1	
Myalgia	v.24.1	
Palpitations	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000965660	0	2021-08-31	2021-08-31	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:		Disability:		Congenital Anomaly:	
Not Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
34 Years	Female	59 Inch	184 Pound	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR			Once	90.0 Days	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Menstruation delayed	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000965663	0	2021-08-31	2021-08-31	Hospital		Spontaneous	Pharmacist

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:	Yes	Hospitalization:		Other Medically Important Conditions:	

Patient Information

Age	Gender	Height	Weight	Report Outcome
37 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Atrial fibrillation	v.24.1	
Myocarditis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000965783	0	2021-09-01	2021-09-01	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
20 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Malaise	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000965785	0	2021-09-01	2021-09-01	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
44 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Axillary pain	v.24.1	
Haematoma	v.24.1	29 Days
Lymphadenopathy	v.24.1	
Myalgia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000965787	0	2021-09-01	2021-09-01	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
66 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Diarrhoea	v.24.1	
Frequent bowel movements	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000965948	1	2021-09-02	2021-09-09	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
34 Years		74 Inch	300 Pound	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR			Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pain	v.24.1	
Pain in extremity	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000965951	0	2021-09-02	2021-09-02	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID 19 VACCINE MODERNA	Suspect				Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Suppressed lactation	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000965954	0	2021-09-02	2021-09-02	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
76 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID 19 VACCINE MODERNA	Suspect				Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dissociation	v.24.1	
Disturbance in attention	v.24.1	
Feeling abnormal	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000965956	0	2021-09-02	2021-09-02	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
65 Years		61 Inch	142 Pound	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	0.5 ml			COVID-19

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.24.1	
Headache	v.24.1	
Musculoskeletal pain	v.24.1	
Nausea	v.24.1	
Pain in extremity	v.24.1	
Peripheral swelling	v.24.1	
Pruritus	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Swollen tongue	v.24.1	
Vaccination site pruritus	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000965957	0	2021-09-02	2021-09-02	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
36 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000966128	0	2021-09-05	2021-09-05	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
16 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
FISH OIL	Concomitant	NOT SPECIFIED					
MULTIVITAMINE(S)	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				COVID-19 prophylaxis
VITAMIN C	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Erythema	v.24.1	
Lymphadenopathy	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Muscle swelling	v.24.1	
Swelling	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000966130	0	2021-09-06	2021-09-06	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
57 Years	Female	64 Inch	140 Pound	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				COVID-19 immunisation
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				COVID-19 immunisation
VAGIFEM	Concomitant	Vaginal suppository					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Burning sensation	v.24.1	
Pruritus	v.24.1	
Rash macular	v.24.1	9 Days
Swelling	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000966133	0	2021-09-04	2021-09-04	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
52 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR					
SYMBICORT	Concomitant	Powder					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Contusion	v.24.1	
Epistaxis	v.24.1	12 Days
Increased tendency to bruise	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000966135	0	2021-09-03	2021-09-03	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
68 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACCUPRIL	Concomitant	Tablets					
ALLOPURINOL	Concomitant	Tablets					
AMLODIPINE	Concomitant	Tablets					
ATORVASTATIN	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				COVID-19 prophylaxis
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR					COVID-19 prophylaxis
SYNTHROID	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Back pain	v.24.1	
Chest discomfort	v.24.1	
Chest pain	v.24.1	
Cough	v.24.1	
Dyspnoea	v.24.1	
Ear pain	v.24.1	
Fatigue	v.24.1	
Headache	v.24.1	
Hypersensitivity	v.24.1	
Pollakiuria	v.24.1	
Pyrexia	v.24.1	
Rash erythematous	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000966136	1	2021-09-06	2021-09-09	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
64 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CALCIUM	Concomitant	NOT SPECIFIED					
CRANBERRY	Concomitant	Tablets					
IRON	Concomitant	NOT SPECIFIED					
OMEGA-3	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml			
VITAMIN B 3	Concomitant	NOT SPECIFIED					
VITAMIN D	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Joint swelling	v.24.1	
Peripheral swelling	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000966141	0	2021-09-03	2021-09-03	Community		Spontaneous	Physician

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
55 Years	Female		70 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	0.5 ml	Once		COVID-19 immunisation
ESTROGEL	Concomitant	GEL					
PROMETRIUM	Concomitant	Capsules					
SERTRALINE	Concomitant	Capsules					
VYVANSE	Concomitant	Capsules					
ZOPICLONE	Concomitant	Tablets					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dyspepsia	v.24.1	
Postmenopausal haemorrhage	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000966145	0	2021-09-03	2021-09-03	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain	v.24.1	
Splenomegaly	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000966149	0	2021-09-03	2021-09-03	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID 19 VACCINE MODERNA	Suspect				Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Ear pain	v.24.1	
Oropharyngeal pain	v.24.1	
Stress	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000966150	0	2021-09-03	2021-09-03	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
67 Years	Female	157 Centimeter	66 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
EZETROL	Concomitant	Tablets					
GABAPENTIN	Concomitant	NOT SPECIFIED					
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	100.0 Microgram			Immunisation
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	100.0 Microgram			Immunisation
OMEPRAZOLE	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hot flush	v.24.1	
Hyperhidrosis	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Vaccination site rash	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000966154	0	2021-09-04	2021-09-04	Community		Spontaneous	Physician

Serious report?	Death:		Disability:	Yes	Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	

Patient Information

Age	Gender	Height	Weight	Report Outcome
56 Years	Female	170 Centimeter	96 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE	Suspect		Intramuscular	0.5 ml	2 every 8 Weeks	58.0 Days	COVID-19 immunisation
PREDNISONE	Concomitant	NOT SPECIFIED					
SYNTHROID	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cardiac failure chronic	v.24.1	
Dyspnoea	v.24.1	
Impaired work ability	v.24.1	
Pulmonary hypertension	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000966157	0	2021-09-05	2021-09-05	Community		Spontaneous	Physician

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
39 Years	Female			Recovering/resolving

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID 19 VACCINE MODERNA	Suspect			0.5 ml	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Herpes zoster	v.24.1	
Neuralgia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000966160	0	2021-09-03	2021-09-03	Hospital		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
67 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CLOZAPINE	Suspect	Tablets	Oral			426.0 Days	
CLOZAPINE	Suspect	Tablets	Oral	350.0 Milligram	1 every 1 Days		
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Antipsychotic drug level increased	v.24.1	
Blood creatinine increased	v.24.1	
Drug interaction	v.24.1	
Pneumonia	v.24.1	
Somnolence	v.24.1	
Therapy change	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000966161	0	2021-09-06	2021-09-06	Community		Spontaneous	Physician

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
13 Years	Male	180 Centimeter	68 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Rash	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000966345	0	2021-09-07	2021-09-07	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
49 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID 19 VACCINE MODERNA	Suspect				Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypokinesia	v.24.1	
Muscle injury	v.24.1	
Musculoskeletal discomfort	v.24.1	
Pain	v.24.1	
Rotator cuff syndrome	v.24.1	
Shoulder injury related to vaccine administration	v.24.1	
Vaccination site swelling	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000966350	0	2021-09-07	2021-09-07	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
49 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Movement disorder	v.24.1	
Muscle injury	v.24.1	
Muscle strain	v.24.1	
Muscle strength abnormal	v.24.1	
Pain	v.24.1	
Rotator cuff syndrome	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:08:27 AM
Initial Received Date:	2021-07-30 to 2021-09-30
Latest Received Date:	N/A
Total Number of Reports:	703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000966351	0	2021-09-07	2021-09-07	Community		Spontaneous	Physician

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
38 Years	Female	64 Inch	114 Pound	Recovering/resolving

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Once		COVID-19

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Back pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:08:27 AM
Initial Received Date:	2021-07-30 to 2021-09-30
Latest Received Date:	N/A
Total Number of Reports:	703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000966526	0	2021-09-08	2021-09-08	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
41 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				COVID-19 immunisation
SYNTHROID	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Breast discomfort	v.24.1	
Breast pain	v.24.1	
Menstrual disorder	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000966531	0	2021-09-08	2021-09-08	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
34 Years	Female	63 Inch	120 Pound	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR			Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Acne	v.24.1	
Eye swelling	v.24.1	
Ocular hyperaemia	v.24.1	
Rash	v.24.1	
Swelling face	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000966532	0	2021-09-08	2021-09-08	Community		Spontaneous	Pharmacist

Serious report?	Death:		Disability:		Congenital Anomaly:	
Not Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
24 Years	Female			Recovering/resolving

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID 19 VACCINE MODERNA	Suspect		Intramuscular	0.5 ml	Once		COVID-19 immunisation
SYNTHROID	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Acne	v.24.1	
Erythema	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000966533	0	2021-09-08	2021-09-08	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
22 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Arthritis	v.24.1	
Blister	v.24.1	
Burning sensation	v.24.1	
Chills	v.24.1	
Erythema	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Gait disturbance	v.24.1	
Haematemesis	v.24.1	
Hyperhidrosis	v.24.1	
Muscle spasms	v.24.1	
Oropharyngeal pain	v.24.1	
Pharyngitis streptococcal	v.24.1	
Pyrexia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000966536	0	2021-09-08	2021-09-08	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
58 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR			Once		
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Feeling hot	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000966541	0	2021-09-08	2021-09-08	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID 19 VACCINE MODERNA	Suspect				Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pericarditis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000966544	0	2021-09-08	2021-09-08	Community		Spontaneous	Pharmacist

Serious report?	Death:		Disability:	Yes	Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
72 Years	Male	67 Inch	85 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	30.0 Microgram			COVID-19 immunisation
STELARA	Concomitant	SOLUTION SUBCUTANEOUS					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Gynaecomastia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000966740	0	2021-09-09	2021-09-09	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
57 Years	Female	163 Centimeter	63 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID 19 VACCINE MODERNA	Suspect						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Loss of consciousness	v.24.1	1 Days
Movement disorder	v.24.1	
Muscle spasms	v.24.1	
Respiration abnormal	v.24.1	
Unresponsive to stimuli	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000966743	0	2021-09-09	2021-09-09	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
44 Years	Female	63 Inch	152 Pound	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dysmenorrhoea	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000966752	0	2021-09-09	2021-09-09	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:	Yes	Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE	Suspect						
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cardio-respiratory arrest	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000966912	0	2021-09-12	2021-09-12	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
36 Years	Female	156 Centimeter	65 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Back pain	v.24.1	20 Days
Feeling cold	v.24.1	
Hypoaesthesia	v.24.1	
Neck pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000966913	0	2021-09-10	2021-09-10	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
50 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Breast mass	v.24.1	
Breast pain	v.24.1	
Breast swelling	v.24.1	
Erythema	v.24.1	
Menstruation irregular	v.24.1	
Oligomenorrhoea	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000966914	0	2021-09-10	2021-09-10	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
35 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID 19 VACCINE MODERNA	Suspect		Intramuscular	0.5 ml	Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Lymph node pain	v.24.1	
Lymphadenopathy	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000966917	0	2021-09-10	2021-09-10	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:		Disability:	Yes	Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	

Patient Information

Age	Gender	Height	Weight	Report Outcome
40 Years	Male	177 Centimeter	91 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID 19 VACCINE MODERNA	Suspect			0.5 ml	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cardiospasm	v.24.1	
Dyspnoea	v.24.1	
Hypoaesthesia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000966918	0	2021-09-10	2021-09-10	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:		Disability:	Yes	Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	

Patient Information

Age	Gender	Height	Weight	Report Outcome
49 Years	Female	67 Inch	190 Pound	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	0.5 ml			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Angina pectoris	v.24.1	
Balance disorder	v.24.1	
Chest discomfort	v.24.1	
Diarrhoea	v.24.1	
Dizziness	v.24.1	
Dyspnoea	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	
Gait disturbance	v.24.1	
Headache	v.24.1	
Hypoaesthesia	v.24.1	
Nausea	v.24.1	
Pain in extremity	v.24.1	
Palpitations	v.24.1	
Tremor	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000966920	1	2021-09-11	2021-09-16	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:		Disability:	Yes	Congenital Anomaly:	
Serious	Life Threatening:	Yes	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
17 Years	Male	184 Centimeter	60 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		COVID-19

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Type 1 diabetes mellitus	v.24.1	24 Days
Vomiting	v.24.1	
Weight decreased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000966922	0	2021-09-11	2021-09-11	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Electric shock sensation	v.24.1	
Pain	v.24.1	
Pain in extremity	v.24.1	
Peripheral coldness	v.24.1	
Tension headache	v.24.1	
Vaccination site pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000967035	0	2021-09-13	2021-09-13	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female	180 Centimeter	50 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR					COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Constipation	v.24.1	
Fatigue	v.24.1	
Headache	v.24.1	
Migraine	v.24.1	
Vision blurred	v.24.1	
Visual impairment	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000967036	0	2021-09-13	2021-09-13	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
26 Years	Female			Recovering/resolving

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Subcutaneous				COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	
Headache	v.24.1	
Pruritus	v.24.1	
Rash	v.24.1	3 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000967037	0	2021-09-13	2021-09-13	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
35 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	000967107

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Vaginal haemorrhage	v.24.1	7 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000967039	0	2021-09-13	2021-09-13	Community		Spontaneous	Physician

Serious report?	Death:	Disability:	Congenital Anomaly:
Not Serious	Life Threatening:	Hospitalization:	Other Medically Important Conditions:

Patient Information

Age	Gender	Height	Weight	Report Outcome
75 Years	Female	155 Centimeter	80 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AMITRIPTYLINE	Concomitant	Tablets					
LIPITOR	Concomitant	NOT SPECIFIED					
METOPROLOL	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once	71.0 Days	
VALSARTAN/HCTZ	Concomitant	Tablets					
XARELTO	Concomitant	Coated tablet					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Rash	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000967040	0	2021-09-13	2021-09-13	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
36 Years	Female	170 Centimeter	120 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				Immunisation
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml			Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Paraesthesia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000967107	0	2021-09-13	2021-09-13	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	000967037

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Transmammary				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Exposure via breast milk	v.24.1	7 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000967255	0	2021-09-14	2021-09-14	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
32 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	000987381

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR		0.3 ml			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abortion spontaneous	v.24.1	7 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000967261	0	2021-09-14	2021-09-14	Hospital		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
31 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID 19 VACCINE MODERNA	Suspect		Intramuscular		Once		Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypotension	v.24.1	
Presyncope	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000967262	0	2021-09-14	2021-09-14	Hospital		Spontaneous	Physician

Serious report?	Death:		Disability:	Yes	Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	

Patient Information

Age	Gender	Height	Weight	Report Outcome
45 Years	Male			Recovering/resolving

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect						COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Deep vein thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000967265	0	2021-09-14	2021-09-14	Hospital		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
31 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
EPIPEN	Concomitant	SOLUTION INTRAMUSCULAR					
LEVOTHYROXINE	Concomitant	Tablets					
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR			Once		
RIVAROXABAN	Concomitant	Film-coated tablet					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Feeling abnormal	v.24.1	
Hypoaesthesia	v.24.1	
Nausea	v.24.1	
Slow speech	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000967268	0	2021-09-14	2021-09-14	Hospital		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
53 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BETADERM	Concomitant	NOT SPECIFIED					
CLOPIDOGREL	Concomitant	Tablets					
METFORMIN	Concomitant	Tablets					
METOPROLOL	Concomitant	Tablets	Unknown				
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				COVID-19 immunisation
TWYNSTA	Concomitant	Tablets					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypertension	v.24.1	
Pruritus	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000967270	0	2021-09-14	2021-09-14	Hospital		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
31 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Once		Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bradycardia	v.24.1	
Presyncope	v.24.1	
Syncope	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000967488	0	2021-09-15	2021-09-15	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
44 Years	Female	173 Centimeter	155 Pound	Recovering/resolving

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intravenous (not otherwise specified)			72.0 Days	COVID-19 immunisation
VENLAFAXINE HYDROCHLORIDE	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Ophthalmic herpes zoster	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000967491	0	2021-09-15	2021-09-15	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
63 Years	Male	69 Inch	67 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR			Once		Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Vaccination site paraesthesia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000967492	0	2021-09-15	2021-09-15	Community		Spontaneous	Physician

Serious report?	Death:		Disability:		Congenital Anomaly:	
Not Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
24 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID 19 VACCINE MODERNA	Suspect						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dehydration	v.24.1	
Dizziness	v.24.1	
Dry throat	v.24.1	
Dyspnoea	v.24.1	
Fatigue	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000967497	0	2021-09-15	2021-09-15	Hospital		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.24.1	
Nausea	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000967515	0	2021-09-08	2021-09-08	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
37 Years	Female	36 Inch		Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE	Suspect		Intramuscular				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Beta haemolytic streptococcal infection	v.24.1	
Chills	v.24.1	
Decreased immune responsiveness	v.24.1	
Dizziness	v.24.1	
Fatigue	v.24.1	
Hand-foot-and-mouth disease	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.24.1	
Migraine	v.24.1	
Pyrexia	v.24.1	
Rash	v.24.1	130 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000967731	0	2021-09-17	2021-09-17	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
40 Years	Female	65 Inch	145 Pound	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Palpitations	v.24.1	
Urticaria	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000967733	0	2021-09-17	2021-09-17	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
54 Years	Male	72 Inch	220 Pound	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.24.1	
Heart rate increased	v.24.1	
Hyperhidrosis	v.24.1	
Palpitations	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000967917	0	2021-09-17	2021-09-17	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
46 Years	Female		180 Pound	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR			Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Autoscopy	v.24.1	
Fatigue	v.24.1	1 Days
Feeling abnormal	v.24.1	
Feeling jittery	v.24.1	
Headache	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000967920	0	2021-09-19	2021-09-19	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
38 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID 19 VACCINE MODERNA	Suspect		Intramuscular		Once	27.0 Days	
TYLENOL	Concomitant	ELIXIR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Skin oedema	v.24.1	
Skin plaque	v.24.1	1 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000967921	0	2021-09-19	2021-09-19	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:		Disability:		Congenital Anomaly:	
Not Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID 19 VACCINE MODERNA	Suspect				Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dysgeusia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000967922	0	2021-09-20	2021-09-20	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
47 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Muscular weakness	v.24.1	
Pain	v.24.1	
Spinal cord haemorrhage	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000968084	0	2021-09-20	2021-09-20	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
57 Years	Female	65 Inch	162 Pound	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal discomfort	v.24.1	
Decreased appetite	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000968087	0	2021-09-20	2021-09-20	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
73 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID VACCINE	Suspect		Intramuscular				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest discomfort	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000968094	0	2021-09-20	2021-09-20	Community		Spontaneous	Pharmacist

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
66 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Once		
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Alopecia areata	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000968310	0	2021-09-21	2021-09-21	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
52 Years	Male	182 Centimeter	90 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID 19 VACCINE MODERNA	Suspect		Intramuscular	0.5 ml	Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Myocarditis	v.24.1	
Pericarditis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000968320	0	2021-09-21	2021-09-21	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
17 Years	Female	162 Centimeter	48 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bell's palsy	v.24.1	
Facial asymmetry	v.24.1	
Hypoaesthesia oral	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000968930	0	2021-09-26	2021-09-26	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
26 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ANTIPSYCHOTIC(S)	Concomitant	NOT SPECIFIED					
CONTRACEPTIVES	Concomitant	NOT SPECIFIED					
COVID 19 VACCINE MODERNA	Suspect		Intramuscular				COVID-19 immunisation
DEPO-PROVERA	Suspect	SUSPENSION INTRAMUSCULAR					
TYLENOL	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.24.1	
Syncope	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000969370	0	2021-09-28	2021-09-28	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
13 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular				COVID-19 prophylaxis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Mobility decreased	v.24.1	
Vulval ulceration	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000969583	0	2021-09-29	2021-09-29	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death: Yes	Disability:	Congenital Anomaly:
Serious	Life Threatening:	Hospitalization:	Other Medically Important Conditions:

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Fatal

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dyspnoea	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04491976	0	2021-07-30	2021-07-30	MAH	MOD-2021-238910	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
73 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	1.0 Dosage forms			COVID-19 immunisation
LEVOTHYROXINE SODIUM	Concomitant	NOT SPECIFIED	Unknown		1 every 1 Days		Thyroid disorder
OMEPRAZOLE	Concomitant	NOT SPECIFIED	Unknown	20.0 Milligram	1 every 1 Days		Gastrooesophageal reflux disease
ROSUVASTATIN	Concomitant	NOT SPECIFIED		100.0 Milligram	1 every 1 Days		Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Heart rate increased	v.24.1	
Ventricular tachycardia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04492693	0	2021-07-30	2021-07-30	MAH	2021A616163	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
39 Years	Female		47 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ALPHA-CAROTENE/BETA-CAROTENE/CALCIUM/IRON/VITAMIN C	Concomitant						
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				COVID-19 immunisation
MRNA-1273 SARS-COV-2	Suspect	NOT SPECIFIED					COVID-19 immunisation
TYLENOL	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Chills	v.24.1	
Fatigue	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Malaise	v.24.1	
Maternal exposure during pregnancy	v.24.1	
Off label use	v.24.1	
Pain in extremity	v.24.1	
Placenta praevia	v.24.1	
Premature delivery	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04493116	1	2021-07-30	2021-08-16	MAH	202100908609	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
47 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Balance disorder	v.24.1	5 Days
Fatigue	v.24.1	5 Days
Gait inability	v.24.1	5 Days
Vertigo	v.24.1	5 Days
Vomiting	v.24.1	5 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04493446	1	2021-07-30	2021-09-14	MAH	2021901155	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
51 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest discomfort	v.24.1	
Dyspnoea exertional	v.24.1	
Palpitations	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04493452	1	2021-07-30	2021-09-13	MAH	2021907755	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
43 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blister	v.24.1	
Condition aggravated	v.24.1	
Feeling hot	v.24.1	
Inflammation	v.24.1	
Lethargy	v.24.1	
Pain	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pain	v.24.1	
Rash pruritic	v.24.1	
Swelling	v.24.1	
Vaccination site pruritus	v.24.1	
Vaccination site rash	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04493709	0	2021-07-30	2021-07-30	MAH	2021908467	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
36 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BETA-CAROTENE/BIOFLAVONOIDS/BIOTIN/CALCIUM ASCORBATE/CALCIUM D-PANTOTHENATE/CALCIUM PHOSPHATE/CHOLINE BITARTRATE/CHROMIC CHLORIDE/COPPER SULFATE/DL-ALPHA TOCOPHERYL ACID SUCCINATE/FOLIC ACID/HESPERIDIN/INOSITOL/IRON AMINO ACID CHELATE	Concomitant						
IRON	Concomitant						

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
VITAMIN D	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Eye inflammation	v.24.1	
Eye injury	v.24.1	
Eye swelling	v.24.1	
Headache	v.24.1	
Seasonal allergy	v.24.1	
Vasodilatation	v.24.1	
Vision blurred	v.24.1	
Visual impairment	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04494261	0	2021-07-30	2021-07-30	MAH	2021523415	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
67 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CALCIUM CARBONATE/VITAMIN D3	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
VITAMIN D	Concomitant		Oral				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.24.1	1 Days
Lymphadenopathy	v.24.1	170 Hours
Nausea	v.24.1	170 Hours

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Vaccination site pain	v.24.1	170 Hours

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04494413	0	2021-07-30	2021-07-30	MAH	21K-028-4013170-00	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
65 Years	Male		67 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular			0.0	COVID-19 prophylaxis
HUMIRA	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous				Product used for unknown indication
HYDROCORTISONE	Concomitant	NOT SPECIFIED	Intravenous (not otherwise specified)	100.0 Milligram			Product used for unknown indication
IMURAN	Suspect	NOT SPECIFIED	Unknown				Product used for unknown indication
INFLIXIMAB	Suspect	NOT SPECIFIED	Intravenous (not otherwise specified)	400.0 Milligram		-143.0	Crohn's disease

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
INFLIXIMAB	Suspect	Powder for injection	Intravenous (not otherwise specified)	400.0 Milligram		-159.0	Crohn's disease
INFLIXIMAB	Suspect	Powder for injection	Intravenous (not otherwise specified)	10.0 mg/kg	1 every 6 Weeks		Crohn's disease
METHOTREXATE	Suspect	NOT SPECIFIED	Unknown				Product used for unknown indication
NIFEDIPINE	Concomitant						Product used for unknown indication
PANTOPRAZOLE	Concomitant	NOT SPECIFIED					Product used for unknown indication
PENTASA	Concomitant	NOT SPECIFIED					Product used for unknown indication
POTASSIUM	Concomitant	NOT SPECIFIED					Product used for unknown indication
PREDNISONE	Concomitant	NOT SPECIFIED					Product used for unknown indication
REMICADE	Suspect	POWDER FOR SOLUTION INTRAVENOUS	Unknown				Product used for unknown indication
TYLENOL	Concomitant	NOT SPECIFIED	Oral	650.0 Milligram		1.0 Days	Product used for unknown indication
VITAMIN B12	Concomitant	NOT SPECIFIED					Product used for unknown indication
VITAMIN D	Concomitant	Capsules					Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest discomfort	v.24.1	
Chest pain	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.24.1	
Crohn's disease	v.24.1	
Drug hypersensitivity	v.24.1	
Drug hypersensitivity	v.24.1	
Drug hypersensitivity	v.24.1	
Drug hypersensitivity	v.24.1	
Fibrin D dimer increased	v.24.1	
Hypoaesthesia	v.24.1	
Livedo reticularis	v.24.1	
Muscle spasms	v.24.1	
Paraesthesia	v.24.1	
Peripheral coldness	v.24.1	
Peripheral embolism	v.24.1	
Pruritus	v.24.1	1 Days
Pulmonary embolism	v.24.1	
Rash	v.24.1	1 Days
Somnolence	v.24.1	
Thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04496536	2	2021-08-02	2021-09-07	MAH	MOD-2021-271430	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
65 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ALVESCO	Concomitant	AEROSOL, METERED DOSE	Unknown				Bronchitis
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	1.0 Dosage forms			COVID-19 immunisation
PREVACID	Concomitant	NOT SPECIFIED	Unknown				Abdominal discomfort
SINGULAIR	Concomitant	NOT SPECIFIED	Unknown				Bronchitis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bronchospasm	v.24.1	
Chest discomfort	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.24.1	
Cough	v.24.1	
Dysphonia	v.24.1	
Dyspnoea	v.24.1	
Erythema	v.24.1	
Eye irritation	v.24.1	
Eye pruritus	v.24.1	
Eye swelling	v.24.1	
Feeling hot	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Mass	v.24.1	
Nausea	v.24.1	
Ocular hyperaemia	v.24.1	
Pruritus	v.24.1	
Rash	v.24.1	
Rhinorrhoea	v.24.1	
Sneezing	v.24.1	
Urticaria	v.24.1	
Vaccination site erythema	v.24.1	
Vaccination site mass	v.24.1	
Vaccination site rash	v.24.1	
Vomiting	v.24.1	
Wheezing	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:08:27 AM
Initial Received Date:	2021-07-30 to 2021-09-30
Latest Received Date:	N/A
Total Number of Reports:	703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04497014	0	2021-08-02	2021-08-02	MAH	MOD-2021-271221	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Unknown	1.0 Dosage forms			COVID-19 immunisation
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	Injection	Unknown	1.0 Dosage forms			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Multiple organ dysfunction syndrome	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04498373	0	2021-08-02	2021-08-02	MAH	2021A652190	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
50 Years	Female	163 Centimeter	77 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Product used for unknown indication
DEXAMETHASONE	Suspect	NOT SPECIFIED	Oral	4.0 Milligram	1 every 1 Days		Immune thrombocytopenia
IMMUNOGLOBULIN G (HUMAN)	Suspect		Intravenous drip			1.0 Days	Platelet count decreased

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Dizziness	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dyspnoea	v.24.1	
Malaise	v.24.1	
Thrombocytopenia	v.24.1	
Vision blurred	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04499302	0	2021-08-02	2021-08-02	MAH	202100922188	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
57 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Months	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blister	v.24.1	
Confusional state	v.24.1	
Deafness	v.24.1	
Drooling	v.24.1	
Fall	v.24.1	
Vertigo	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04499377	0	2021-08-02	2021-08-02	MAH	202100935041	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
17 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Myocarditis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04499556	0	2021-08-02	2021-08-02	MAH	202100909701	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
49 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Neck pain	v.24.1	
Sudden hearing loss	v.24.1	
Tinnitus	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04500593	2	2021-08-03	2021-09-06	MAH	2021A649918	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
55 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Ageusia	v.24.1	
Anosmia	v.24.1	
Asthenia	v.24.1	
Chills	v.24.1	
Confusional state	v.24.1	5 Days
Diarrhoea	v.24.1	2 Weeks

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Ear pain	v.24.1	
Eye pruritus	v.24.1	
Furuncle	v.24.1	
Gait disturbance	v.24.1	
Headache	v.24.1	
Hyperhidrosis	v.24.1	
Hypersensitivity	v.24.1	
Hypertension	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Nasal obstruction	v.24.1	
Pain	v.24.1	
Pain in extremity	v.24.1	
Pyrexia	v.24.1	
Sinus congestion	v.24.1	
Sweat gland disorder	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04500972	0	2021-08-03	2021-08-03	MAH	MOD-2021-260288	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Unknown	1.0 Dosage forms			COVID-19 immunisation
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	Injection	Unknown	1.0 Dosage forms			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain	v.24.1	
Chest pain	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Gallbladder rupture	v.24.1	
Inappropriate schedule of product administration	v.24.1	58 Days
Infection	v.24.1	
Nausea	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04501753	1	2021-08-03	2021-11-17	MAH	2874724	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
59 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACTEMRA	Suspect	Solution for injection in pre-filled syringe	Subcutaneous	162.0 Milligram	1 every 6 Weeks		Rheumatoid arthritis
ACTEMRA	Suspect	NOT SPECIFIED	Subcutaneous	162.0 Milligram	1 every 4 Weeks		Rheumatoid arthritis
ACTEMRA	Suspect	Solution for injection in pre-filled syringe	Subcutaneous	162.0 Milligram	1 every 2 Weeks		Rheumatoid arthritis
ARAVA	Concomitant	Tablets					
COLACE	Concomitant	NOT SPECIFIED					

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				Product used for unknown indication
IRON	Concomitant						
NAPROXEN	Concomitant	NOT SPECIFIED	Unknown				
PANTOPRAZOLE	Concomitant	NOT SPECIFIED					
PREDNISONE	Concomitant	NOT SPECIFIED					
TYLENOL ARTHRITIS PAIN 8H	Concomitant	TABLET (EXTENDED-RELEASE)					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Headache	v.24.1	
Joint swelling	v.24.1	1 Days
Low density lipoprotein increased	v.24.1	
Mean cell haemoglobin decreased	v.24.1	
Mean cell volume decreased	v.24.1	
Periorbital pain	v.24.1	
Renal impairment	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04502484	1	2021-08-03	2021-08-24	MAH	20210750176	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
23 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				Product used for unknown indication
PALIPERIDONE PALMITATE	Suspect		Intramuscular		1 every 1 Months		Product used for unknown indication
PALIPERIDONE PALMITATE	Suspect	Injection	Intramuscular	100.0 Milligram	1 every 4 Weeks		Product used for unknown indication
QUETIAPINE	Concomitant	Tablets					Product used for unknown indication
ZOPICLONE	Concomitant	Tablets		5.0 Milligram			Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pulmonary embolism	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04502719	0	2021-08-03	2021-08-03	MAH	202100923659	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
34 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Chills	v.24.1	
Dyspnoea	v.24.1	
Fatigue	v.24.1	
Headache	v.24.1	
Increased appetite	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Irritability	v.24.1	
Pulmonary congestion	v.24.1	
Pyrexia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04503514	1	2021-08-03	2021-09-06	MAH	2021654701	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
63 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BUDESONIDE/FORMOTEROL FUMARATE	Concomitant		Inhalation	200.0 Microgram			Asthma
LIOTHYRONINE SODIUM	Concomitant		Oral				Autoimmune thyroiditis
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
SYNTHROID	Concomitant	NOT SPECIFIED	Oral	0.075 Microgram			Hypothyroidism, Autoimmune thyroiditis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.24.1	9005 Minutes

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	
Headache	v.24.1	3245 Minutes
Insomnia	v.24.1	
Nausea	v.24.1	9005 Minutes
Night sweats	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04503569	1	2021-08-03	2021-09-16	MAH	202100917971	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
37 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Testicular swelling	v.24.1	
Testis discomfort	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:08:27 AM
Initial Received Date:	2021-07-30 to 2021-09-30
Latest Received Date:	N/A
Total Number of Reports:	703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04503574	1	2021-08-03	2021-08-17	MAH	202100917683	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
59 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
FAMPYRA	Concomitant	TABLET (EXTENDED-RELEASE)	Oral				Multiple sclerosis
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
TECFIDERA	Concomitant	NOT SPECIFIED	Oral				Multiple sclerosis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Gait inability	v.24.1	40 Days
Inappropriate schedule of product administration	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Multiple sclerosis relapse	v.24.1	41 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04503582	1	2021-08-03	2021-09-16	MAH	202100933417	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
53 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
INFLIXIMAB	Concomitant			300.0 Milligram			Crohn's disease
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Months	COVID-19 immunisation
PREDNISONE	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Crohn's disease	v.24.1	
Crying	v.24.1	
Fatigue	v.24.1	
Post procedural infection	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Skin laceration	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04503586	0	2021-08-03	2021-08-03	MAH	202100923052	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
78 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETYLSALICYLIC ACID	Concomitant		Oral				Anticoagulant therapy
AMLODIPINE	Concomitant	Tablets	Oral				Cardiac disorder
LATANOPROST	Concomitant	SOLUTION OPHTHALMIC	Ophthalmic				Glaucoma
METOPROLOL	Concomitant		Oral				Cardiac disorder, Blood pressure abnormal
METOPROLOL	Concomitant		Oral				Cardiac disorder, Blood pressure abnormal
NITROGEN	Concomitant		Ophthalmic				Glaucoma

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
NORVASK [AMLODIPINE]	Concomitant		Oral				Coagulopathy
OXAZEPAM	Concomitant	Tablets	Oral				Anxiety
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
ROSUVASTATIN	Concomitant	NOT SPECIFIED	Oral				Blood cholesterol abnormal
SYNTHROID	Concomitant	NOT SPECIFIED	Oral				Thyroid disorder

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	5 Days
Cardiac disorder	v.24.1	5 Days
Chest pain	v.24.1	5 Days
Discomfort	v.24.1	5 Days
Inappropriate schedule of product administration	v.24.1	
Malaise	v.24.1	5 Days
Morbid thoughts	v.24.1	5 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04503609	0	2021-08-03	2021-08-03	MAH	202100917086	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
44 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
VISANNE	Concomitant	Tablets	Oral				Endometriosis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Injected limb mobility decreased	v.24.1	
Tendon disorder	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04503614	0	2021-08-03	2021-08-03	MAH	202100934039	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
67 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
B12 [CYANOCOBALAMIN]	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown			1.0 Days	COVID-19 immunisation
RABEPRAZOLE SODIUM	Concomitant						
SYNTHROID	Concomitant	NOT SPECIFIED					
ZOPICLONE	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	
Inappropriate schedule of product administration	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Lymphadenopathy	v.24.1	
Nausea	v.24.1	
Peripheral swelling	v.24.1	
Swelling face	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04503620	0	2021-08-03	2021-08-03	MAH	202100923711	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
64 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CISPLATIN	Concomitant		Intravenous (not otherwise specified)				Rheumatoid arthritis
ENBREL	Concomitant		Intravenous (not otherwise specified)				Rheumatoid arthritis
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hemiplegia	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypoaesthesia	v.24.1	
Seizure	v.24.1	
Subdural haematoma	v.24.1	
Thrombocytopenia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04503735	0	2021-08-03	2021-08-03	MAH	202100941047	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
45 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
LEVOTHYROXINE SODIUM	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Burning sensation	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Pruritus	v.24.1	
Rash	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:08:27 AM
Initial Received Date:	2021-07-30 to 2021-09-30
Latest Received Date:	N/A
Total Number of Reports:	703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04504890	1	2021-08-03	2021-08-10	MAH	202100923587	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
48 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthritis	v.24.1	
Dyspnoea	v.24.1	4 Hours
Hypoaesthesia	v.24.1	
Mobility decreased	v.24.1	
Pain in extremity	v.24.1	
Peripheral swelling	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Syncope	v.24.1	1 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04505282	0	2021-08-04	2021-08-04	MAH	CA2021AMR157327	Study	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
77 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_04625526
Linked	E2B_03110858

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AZITHROMYCIN	Suspect	NOT SPECIFIED	Unknown				Product used for unknown indication
COVID-19 VACCINE	Suspect		Unknown				COVID-19 prophylaxis
MEPOLIZUMAB	Suspect		Subcutaneous	100.0 Milligram		480.0 Days	Asthma

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cough	v.24.1	
Dyspnoea	v.24.1	
Hospitalisation	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Inappropriate schedule of product administration	v.24.1	1 Days
Nasopharyngitis	v.24.1	
Pain in extremity	v.24.1	
Product dose omission issue	v.24.1	
Sneezing	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04506240	0	2021-08-04	2021-08-04	MAH	MOD-2021-272523	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Unknown	1.0 Dosage forms			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hospitalisation	v.24.1	8 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04506401	0	2021-08-04	2021-08-04	MAH	MOD-2021-270859	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
23 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	1.0 Dosage forms			COVID-19 immunisation
TOZINAMERAN	Suspect		Intramuscular	1.0 Dosage forms			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Influenza like illness	v.24.1	
Interchange of vaccine products	v.24.1	
Loss of consciousness	v.24.1	
Pain in extremity	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04507344	1	2021-08-04	2021-09-21	MAH	20210756389	Study	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_03704626
Linked	
Linked	E2B_03704626

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				COVID-19 prophylaxis
REMICADE	Suspect	POWDER FOR SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)		1 every 6 Weeks		Colitis ulcerative

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthritis infective	v.24.1	
Fatigue	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04507921	1	2021-08-04	2021-09-17	MAH	202100934154	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
38 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pyrexia	v.24.1	
Tonsillitis	v.24.1	
Urinary tract infection	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04507922	0	2021-08-04	2021-08-04	MAH	202100934875	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
40 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Retinal tear	v.24.1	
Visual impairment	v.24.1	
Vitreous floaters	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04507927	2	2021-08-04	2021-09-15	MAH	202100922825	Spontaneous	Consumer/other non health professional

Serious report?
Serious

Death:	No	**Disability:**	No	**Congenital Anomaly:**	No
Life Threatening:	Yes	**Hospitalization:**	No	**Other Medically Important Conditions:**	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_04507910
Linked	E2B_04507910
Linked	E2B_04507910
Linked	E2B_04507910

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.24.1	
Blindness	v.24.1	
Cerebrovascular accident	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:08:27 AM
Initial Received Date:	2021-07-30 to 2021-09-30
Latest Received Date:	N/A
Total Number of Reports:	703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04507943	1	2021-08-04	2021-09-15	MAH	202100921858	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
16 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Myocarditis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04508006	0	2021-08-04	2021-08-04	MAH	202100930238	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
55 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BISOPROLOL	Concomitant						
LASIX [FUROSEMIDE]	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
ROSUVASTATIN CALCIUM	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.24.1	6 Days
Neck pain	v.24.1	
Pain in extremity	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04508161	0	2021-08-04	2021-08-04	MAH	202100929224	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
74 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
LEVOTHYROXINE SODIUM	Concomitant	NOT SPECIFIED		125.0 Milligram			
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Diarrhoea	v.24.1	
Inappropriate schedule of product administration	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04508307	0	2021-08-04	2021-08-04	MAH	202100941550	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
37 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	E2B_04509824
Linked	E2B_04509824

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abortion spontaneous	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04508445	0	2021-08-04	2021-08-04	MAH	2021BI01032859	Study	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
57 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Unknown				COVID-19 prophylaxis
PLEGRIDY PRE-FILLED SYRINGE OR PRE-FILLED PEN	Suspect	Unknown	Subcutaneous	125.0 Microgram	1 every 3 Weeks		Relapsing-remitting multiple sclerosis
PLEGRIDY PRE-FILLED SYRINGE OR PRE-FILLED PEN	Suspect	LIQUID SUBCUTANEOUS	Subcutaneous	125.0 Microgram	1 every 3 Weeks		Relapsing-remitting multiple sclerosis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Drug delivery system malfunction	v.24.1	
Drug dose omission by device	v.24.1	
Underdose	v.24.1	
Vaccination complication	v.24.1	
White blood cell count decreased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04509091	1	2021-08-04	2021-09-01	MAH	202100933553	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
13 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Deafness unilateral	v.24.1	
Dizziness	v.24.1	
Headache	v.24.1	
Tinnitus	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04509354	0	2021-08-04	2021-08-04	MAH	MOD-2021-272110	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
41 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	1.0 Dosage forms			COVID-19 immunisation
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	Injection	Unknown	1.0 Dosage forms			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chorioretinopathy	v.24.1	
Eye inflammation	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Eye pruritus	v.24.1	
Ocular discomfort	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04509787	0	2021-08-04	2021-08-04	MAH	202100934962	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
36 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dysmenorrhoea	v.24.1	
Heavy menstrual bleeding	v.24.1	
Oligomenorrhoea	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04509824	1	2021-08-04	2021-09-16	MAH	202100991812	Spontaneous	Consumer/other non health professional

Serious report?
Serious

Death:	Yes	**Disability:**	No	**Congenital Anomaly:**	Yes
Life Threatening:	No	**Hospitalization:**	No	**Other Medically Important Conditions:**	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Fatal

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_04629806
Linked	E2B_04629806
Linked	E2B_04508307
Linked	E2B_04508307

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Transplacental		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Foetal growth abnormality	v.24.1	
Maternal exposure during pregnancy	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04510385	0	2021-08-05	2021-08-05	MAH	CA2021AMR165431	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
67 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	E2B_01823996
Linked	
Linked	
Linked	E2B_02863411
Linked	E2B_02157010
Linked	E2B_02039467
Linked	
Linked	
Linked	E2B_02657395
Linked	E2B_01915300

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ADVAIR	Concomitant	NOT SPECIFIED	Unknown	1.0 Dosage forms	2 every 1 Days		Product used for unknown indication

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AZITHROMYCIN	Concomitant		Unknown				Product used for unknown indication
COVID-19 VACCINE	Suspect		Unknown				Prophylaxis
MEPOLIZUMAB	Suspect		Subcutaneous	100.0 Milligram			Asthma
VENTOLIN	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.24.1	2 Days
Pneumonia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04510903	0	2021-08-05	2021-08-05	MAH	CA2021AMR166250	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
66 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				COVID-19 prophylaxis
MEPOLIZUMAB	Suspect		Subcutaneous	100.0 Milligram			Asthma

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Colitis	v.24.1	
Cystitis	v.24.1	
Nephrolithiasis	v.24.1	
Urticaria	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:08:27 AM
Initial Received Date:	2021-07-30 to 2021-09-30
Latest Received Date:	N/A
Total Number of Reports:	703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04512834	1	2021-08-05	2021-09-14	MAH	202100929904	Spontaneous	Physician

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
93 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CALCIUM ACETATE	Concomitant	Tablet	Oral	500.0 Milligram			
LEVOTHYROXINE SODIUM	Concomitant		Oral	25.0 Microgram			
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
THYROXINE	Concomitant	NOT SPECIFIED	Oral				
VITAMIN D3	Concomitant		Oral				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Angina pectoris	v.24.1	
Arthralgia	v.24.1	
Arthralgia	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bone pain	v.24.1	
Chest pain	v.24.1	
Fall	v.24.1	
Hyponatraemia	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Loss of personal independence in daily activities	v.24.1	
Mobility decreased	v.24.1	
Myocarditis	v.24.1	
Rib fracture	v.24.1	
Spinal pain	v.24.1	
Thrombosis	v.24.1	
Urinary tract infection	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04512862	1	2021-08-05	2021-08-19	MAH	202100935042	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
35 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
LISDEXAMFETAMINE DIMESYLATE	Concomitant		Oral	30.0 Milligram			Attention deficit hyperactivity disorder
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hallucination	v.24.1	7 Days
Paranoia	v.24.1	7 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04512929	0	2021-08-05	2021-08-05	MAH	202100942068	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
31 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Burning sensation	v.24.1	
Erythema	v.24.1	
Paraesthesia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04513101	1	2021-08-05	2021-09-16	MAH	202100967981	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
24 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CONCERTA	Concomitant	TABLET (EXTENDED-RELEASE)					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Inappropriate schedule of product administration	v.24.1	
Pneumothorax	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04513122	0	2021-08-05	2021-08-05	MAH	202100968828	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
39 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Aplastic anaemia	v.24.1	
Ecchymosis	v.24.1	
Petechiae	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:08:27 AM
Initial Received Date:	2021-07-30 to 2021-09-30
Latest Received Date:	N/A
Total Number of Reports:	703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04514095	1	2021-08-05	2021-11-26	MAH	20210758954	Study	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
51 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	
Linked	
Linked	
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				COVID-19 prophylaxis
REMICADE	Suspect	POWDER FOR SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	450.0 Milligram			Product used for unknown indication, Colitis ulcerative
REMICADE	Suspect	Solution for infusion	Intravenous (not otherwise specified)				Product used for unknown indication, Colitis ulcerative

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anal abscess	v.24.1	
Body temperature increased	v.24.1	
Diarrhoea	v.24.1	
Frequent bowel movements	v.24.1	
General physical health deterioration	v.24.1	
Haematochezia	v.24.1	
Haemorrhoids	v.24.1	
Infusion related reaction	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04514226	2	2021-08-05	2021-10-27	MAH	20210759307	Study	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
18 Years	Male		149 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				COVID-19 prophylaxis
REMICADE	Suspect	POWDER FOR SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	600.0 Milligram	1 every 8 Weeks		Crohn's disease

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Crohn's disease	v.24.1	
Dizziness	v.24.1	
Incorrect dose administered	v.24.1	
Off label use	v.24.1	
Pneumonia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04514229	0	2021-08-05	2021-08-05	MAH	20210759223	Study	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
84 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	
Linked	
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown			1.0 Months	COVID-19 prophylaxis
REMICADE	Suspect	POWDER FOR SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)				Rheumatoid arthritis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cellulitis	v.24.1	1 Months

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04514759	0	2021-08-05	2021-08-05	MAH	CANSL2021101404	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
66 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				Product used for unknown indication
COVID-19 VACCINE	Suspect		Unknown				Product used for unknown indication
ENBREL	Suspect		Unknown	25.0 Milligram	2 every 1 Weeks		Rheumatoid arthritis
ENBREL	Suspect	Powder and solvent for solution for injection	Unknown	50.0 Milligram			Rheumatoid arthritis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cystitis	v.24.1	
Discomfort	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Endodontic procedure	v.24.1	
Labelled drug-drug interaction issue	v.24.1	
Tooth infection	v.24.1	
Urinary tract infection	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04518268	1	2021-08-06	2021-09-14	MAH	202100942270	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
41 Years	Male	174 Centimeter	56 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CETIRIZINE HYDROCHLORIDE	Concomitant		Oral	10.0 Milligram			
IBUPROFEN	Concomitant	NOT SPECIFIED			2 every 1 Days		
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
PREDNISONE	Concomitant	NOT SPECIFIED		60.0 Milligram	every 1 Days		
TOBRAMYCIN	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bell's palsy	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Extraocular muscle paresis	v.24.1	
Headache	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Muscular weakness	v.24.1	
Pain in jaw	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04518270	0	2021-08-06	2021-08-06	MAH	202100942251	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
55 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
PRUCALOPRIDE	Concomitant			5.0 Milligram	every 1 Days		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Inappropriate schedule of product administration	v.24.1	
Postmenopausal haemorrhage	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04518271	0	2021-08-06	2021-08-06	MAH	202100941788	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
50 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.24.1	
Inflammation	v.24.1	
Pain in extremity	v.24.1	8 Hours
Vein disorder	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04518282	1	2021-08-06	2021-08-24	MAH	202100940587	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
63 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
VEDOLIZUMAB	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Aphasia	v.24.1	
Catatonia	v.24.1	
Cerebrovascular accident	v.24.1	
Confusional state	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04518288	1	2021-08-06	2021-09-10	MAH	202100957883	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
78 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Skin exfoliation	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04518316	0	2021-08-06	2021-08-06	MAH	202100956151	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
45 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cardiac disorder	v.24.1	
Thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04518554	1	2021-08-06	2021-09-15	MAH	202100962615	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
21 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
QUETIAPINE FUMARATE	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Labyrinthitis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04518883	1	2021-08-06	2021-08-10	MAH	202100978578	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
39 Years	Male			Recovered/resolved with sequelae

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic shock	v.24.1	
Erythema	v.24.1	
Flushing	v.24.1	
Loss of consciousness	v.24.1	
Throat irritation	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04520924	0	2021-08-06	2021-08-06	MAH	MOD-2021-132722	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
78 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CLONAZEPAM	Concomitant	Tablets	Unknown	0.5 Milligram	1 every 1 Hours		Product used for unknown indication
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	1.0 Dosage forms			COVID-19 immunisation
TRANDOLAPRIL	Concomitant		Unknown	2.5 Milligram	1 every 1 Days		Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Angioedema	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Product dose omission issue	v.24.1	
Suffocation feeling	v.24.1	
Swelling face	v.24.1	
Vaccination site pain	v.24.1	
Vaccination site swelling	v.24.1	
Vaccination site warmth	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04521983	1	2021-08-06	2021-09-03	MAH	2021872045	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
82 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETAMINOPHEN	Concomitant	Tablet		650.0 Milligram			
BISOPROLOL	Concomitant	Tablets	Oral	2.5 Milligram	every 1 Days		
ELIQUIS FILM COATED	Concomitant	Tablets		5.0 Milligram	2 every 1 Days		
ENALAPRIL MALEATE	Concomitant	Tablet	Oral	10.0 Milligram	2 every 1 Days		
FLUTICASONE PROPIONATE/SALMETEROL XINAFOATE	Concomitant						
HYDROXYCHLOROQUINE SULFATE	Concomitant			200.0 Milligram	2 every 1 Days		
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
PLANTAGO OVATA	Concomitant						

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PREDNISONE	Concomitant	NOT SPECIFIED		10.0 Milligram	every 1 Days		Rheumatoid arthritis
SPIRONOLACTONE	Concomitant	Tablets	Oral	12.5 Milligram	every 1 Days		
SULFASALAZINE	Concomitant	NOT SPECIFIED		1.0 Gram	2 every 1 Days		
TECTA	Concomitant	NOT SPECIFIED		40.0 Milligram			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Joint swelling	v.24.1	
Malaise	v.24.1	
Pain in extremity	v.24.1	
Peripheral swelling	v.24.1	
Rheumatoid arthritis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04526131	0	2021-08-09	2021-08-09	MAH	20210761714	Study	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
19 Years	Male		80 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				COVID-19 prophylaxis
FOLIC ACID	Concomitant		Unknown				Product used for unknown indication
METHOTREXATE	Concomitant	NOT SPECIFIED	Unknown	10.0 Milligram	1 every 1 Weeks		Product used for unknown indication
REMICADE	Suspect	POWDER FOR SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	800.0 Milligram	1 every 8 Weeks		Crohn's disease

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Respiratory tract infection	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04526235	0	2021-08-09	2021-08-09	MAH	2021A672178	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
60 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
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Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Product used for unknown indication
AZITHROMYCIN	Concomitant	NOT SPECIFIED					
FORMOTEROL FUMARATE/MOMETASONE FUROATE	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Deep vein thrombosis	v.24.1	
Heparin-induced thrombocytopenia test positive	v.24.1	
Pulmonary embolism	v.24.1	
Thrombocytopenia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04526315	0	2021-08-09	2021-08-09	MAH	2021A672147	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
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Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.5 ml			Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anti-platelet antibody	v.24.1	
Chest pain	v.24.1	
Chills	v.24.1	
Dyspnoea	v.24.1	
Pulmonary embolism	v.24.1	
Thrombocytopenia	v.24.1	
Thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04526349	0	2021-08-09	2021-08-09	MAH	2021A672158	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
50 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
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Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.5 ml			Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Deep vein thrombosis	v.24.1	
Immune thrombocytopenia	v.24.1	
Pulmonary embolism	v.24.1	
Thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04526441	0	2021-08-09	2021-08-09	MAH	2021A672169	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
70 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
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Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.5 ml			Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Deep vein thrombosis	v.24.1	34 Days
Heparin-induced thrombocytopenia test positive	v.24.1	34 Days
Superficial vein prominence	v.24.1	34 Days
Thrombocytopenia	v.24.1	34 Days
Thrombosis	v.24.1	34 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04526445	2	2021-08-09	2021-09-01	MAH	2021A671531	Spontaneous	Other health professional

Serious report?
Serious

Death:	No	**Disability:**	No	**Congenital Anomaly:**	No
Life Threatening:	No	**Hospitalization:**	Yes	**Other Medically Important Conditions:**	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
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Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cerebral venous sinus thrombosis	v.24.1	
Thrombocytopenia	v.24.1	
Thrombosis	v.24.1	
Thrombotic thrombocytopenic purpura	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04526468	0	2021-08-09	2021-08-09	MAH	2021A672100	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
50 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
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Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cerebral venous sinus thrombosis	v.24.1	
Headache	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Heparin-induced thrombocytopenia test positive	v.24.1	
Hyperhidrosis	v.24.1	
Nausea	v.24.1	
Thrombocytopenia	v.24.1	
Thrombosis	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04526640	0	2021-08-09	2021-08-09	MAH	2021A672069	Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
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Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Product used for unknown indication
NAPROXEN	Concomitant	NOT SPECIFIED	Unknown				
SALBUTAMOL	Concomitant	NOT SPECIFIED	Unknown				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anti-platelet antibody positive	v.24.1	10 Days
Cerebrovascular accident	v.24.1	10 Days
Thrombocytopenia	v.24.1	10 Days
Thrombosis	v.24.1	10 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04526644	0	2021-08-09	2021-08-09	MAH	2021A672191	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
50 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
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Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.5 ml			Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Brain injury	v.24.1	
Heparin-induced thrombocytopenia test positive	v.24.1	
Post procedural stroke	v.24.1	
Subdural haematoma	v.24.1	
Thrombocytopenia	v.24.1	
Thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04526734	0	2021-08-09	2021-08-09	MAH	2021A671499	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
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Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.24.1	18 Days
Dyspnoea exertional	v.24.1	18 Days
Heparin-induced thrombocytopenia test positive	v.24.1	18 Days
Pulmonary embolism	v.24.1	18 Days
Thrombocytopenia	v.24.1	18 Days
Thrombotic thrombocytopenic purpura	v.24.1	18 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04526807	1	2021-08-09	2021-09-07	MAH	202100957086	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
62 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AMLODIPINE	Concomitant	Tablets					
ATENOLOL	Concomitant	Tablets					
FLUOXETINE	Concomitant	NOT SPECIFIED					
FUROSEMIDE	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.24.1	
Influenza like illness	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Interchange of vaccine products	v.24.1	
Limb discomfort	v.24.1	
Malaise	v.24.1	
Movement disorder	v.24.1	
Off label use	v.24.1	
Pain in extremity	v.24.1	
Peripheral swelling	v.24.1	
Rash pruritic	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04526862	0	2021-08-09	2021-08-09	MAH	202100943675	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
54 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
VORTIOXETINE	Concomitant			5.0 Milligram			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypoaesthesia	v.24.1	
Pharyngeal swelling	v.24.1	
Swollen tongue	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04526921	0	2021-08-09	2021-08-09	MAH	202100963003	Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
45 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Months	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bell's palsy	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04527010	0	2021-08-09	2021-08-09	MAH	2021A671980	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
40 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
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Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.5 ml			Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anti-platelet antibody positive	v.24.1	
Thrombocytopenia	v.24.1	
Thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04527096	0	2021-08-09	2021-08-09	MAH	202100942837	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
62 Years	Female			Recovered/resolved with sequelae

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AMLODIPINE BESILATE/PERINDOPRIL ARGININE	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
VAGIFEM	Concomitant	Vaginal suppository		10.0 Milligram			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cardiac flutter	v.24.1	
Heart rate increased	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Presyncope	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04527412	0	2021-08-09	2021-08-09	MAH	2021A671670	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
50 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
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Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Heparin-induced thrombocytopenia test positive	v.24.1	
Incomplete course of vaccination	v.24.1	
Pyrexia	v.24.1	
Thrombocytopenia	v.24.1	
Thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04527631	0	2021-08-09	2021-08-09	MAH	2021A672060	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
60 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
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Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cerebral venous sinus thrombosis	v.24.1	
Dizziness	v.24.1	
Headache	v.24.1	
Heparin-induced thrombocytopenia test positive	v.24.1	
Nausea	v.24.1	
Pain in jaw	v.24.1	
Paranasal sinus discomfort	v.24.1	
Photophobia	v.24.1	
Thrombocytopenia	v.24.1	
Thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04527655	0	2021-08-09	2021-08-09	MAH	2021690827	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
54 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CALCIUM	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
VITAMIN E [VITAMIN E NOS]	Concomitant						
ZINC	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood urine present	v.24.1	
Postmenopausal haemorrhage	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04527740	0	2021-08-09	2021-08-09	MAH	202100968380	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
49 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
PROZAC	Concomitant	NOT SPECIFIED	Oral	40.0 Milligram	every 1 Days		Depression
TRYPTOLINE	Concomitant		Oral				Insomnia

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Lower respiratory tract infection	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04527745	0	2021-08-09	2021-08-09	MAH	202100949621	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
30 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
IBUPROFEN	Concomitant						
NAPROXEN	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
TYLENOL	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Decreased appetite	v.24.1	
Dizziness	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Eye pain	v.24.1	
Fatigue	v.24.1	
Headache	v.24.1	
Injection site swelling	v.24.1	
Lymphadenopathy	v.24.1	
Pyrexia	v.24.1	
Vision blurred	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04527873	0	2021-08-09	2021-08-09	MAH	202100951292	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
30 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	1 Months
Influenza like illness	v.24.1	1 Months
Maternal exposure during pregnancy	v.24.1	
Mobility decreased	v.24.1	1 Months
Mouth ulceration	v.24.1	1 Months
Vaginal ulceration	v.24.1	1 Months

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04527876	0	2021-08-09	2021-08-09	MAH	202100956380	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
14 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Immune thrombocytopenia	v.24.1	
Syncope	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04528582	1	2021-08-09	2021-08-25	MAH	202100950396	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
31 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Heavy menstrual bleeding	v.24.1	
Localised infection	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04528594	0	2021-08-09	2021-08-09	MAH	202100957415	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
40 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Fatigue	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Pain in extremity	v.24.1	
Restless legs syndrome	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04528733	0	2021-08-09	2021-08-09	MAH	2021A672048	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
50 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
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Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Acute myocardial infarction	v.24.1	
Chest pain	v.24.1	
Coronary artery thrombosis	v.24.1	
Headache	v.24.1	
Heparin-induced thrombocytopenia test positive	v.24.1	
Myalgia	v.24.1	
Neck pain	v.24.1	
Paraesthesia	v.24.1	
Thrombocytopenia	v.24.1	
Vision blurred	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04528737	0	2021-08-09	2021-08-09	MAH	202100985362	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
69 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AMLODIPINE BESILATE	Concomitant			5.0 Milligram			
LIPITOR	Concomitant	NOT SPECIFIED		20.0 Milligram			
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown			1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Inappropriate schedule of product administration	v.24.1	
Pericardial effusion	v.24.1	
Pericardial fibrosis	v.24.1	
Pericarditis	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pleural effusion	v.24.1	
Weight increased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04529284	0	2021-08-09	2021-08-09	MAH	2021A672215	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
50 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Adrenal haemorrhage	v.24.1	
Adrenal insufficiency	v.24.1	
Asthenia	v.24.1	
Back pain	v.24.1	
Carotid artery thrombosis	v.24.1	
Cerebral infarction	v.24.1	
Cerebral venous sinus thrombosis	v.24.1	
Cold sweat	v.24.1	
Depressed level of consciousness	v.24.1	
Haemorrhage	v.24.1	
Heparin-induced thrombocytopenia test positive	v.24.1	
Hypotension	v.24.1	
Pelvic venous thrombosis	v.24.1	
Pulmonary embolism	v.24.1	
Renal vascular thrombosis	v.24.1	
Thrombocytopenia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04530525	4	2021-08-10	2021-11-05	MAH	20210205854	Study	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
50 Years	Female		102 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_01772497
Linked	
Linked	E2B_01772497
Linked	
Linked	E2B_01772497
Linked	
Linked	
Linked	E2B_01772497
Linked	
Linked	E2B_01772497

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AMOXICILLIN	Suspect	NOT SPECIFIED	Unknown				Mastoiditis
COVID-19 VACCINE	Suspect		Unknown			1.0 Months	COVID-19 prophylaxis

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
REMICADE	Suspect	POWDER FOR SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	600.0 Milligram	1 every 6 Weeks		Cogan's syndrome
REMICADE	Suspect	Solution for infusion	Intravenous (not otherwise specified)	500.0 Milligram	1 every 8 Weeks		Cogan's syndrome
REMICADE	Suspect	Solution for infusion	Intravenous (not otherwise specified)	500.0 Milligram	1 every 6 Weeks		Cogan's syndrome

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthritis	v.24.1	1 Days
Drug hypersensitivity	v.24.1	
Ear infection	v.24.1	
Lymphoedema	v.24.1	1 Days
Mastoiditis	v.24.1	13 Days
Nonspecific reaction	v.24.1	1 Days
Psoriasis	v.24.1	
Type IV hypersensitivity reaction	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04530645	1	2021-08-10	2021-12-20	MAH	CANSL2021121452	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
65 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_04554662

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				Prophylaxis
ENBREL	Suspect		Unknown				Rheumatoid arthritis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Seizure	v.24.1	
Unevaluable event	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04530754	2	2021-08-10	2021-09-13	MAH	2021A674573	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female	170 Centimeter	46 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Product used for unknown indication
BACLOFEN	Concomitant	Tablet	Unknown				
BUDESONIDE/FORMOTEROL FUMARATE	Concomitant		Unknown				
CIMETIDINE	Concomitant	Tablet	Unknown				
EPINEPHRINE HYDROCHLORIDE	Concomitant		Unknown				
EZETROL	Concomitant	Tablets	Unknown				
FUROSEMIDE	Concomitant	NOT SPECIFIED	Unknown				
GABAPENTIN	Concomitant	NOT SPECIFIED	Unknown				
JANUVIA	Concomitant	NOT SPECIFIED	Unknown				
LAMISIL	Concomitant	NOT SPECIFIED	Unknown				

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
LANTUS	Concomitant	SOLUTION SUBCUTANEOUS	Unknown				
LODALIS	Concomitant	POWDER FOR SUSPENSION ORAL	Unknown				
LOPERAMIDE HYDROCHLORIDE	Concomitant	Tablet	Unknown				
MONTELUKAST SODIUM	Concomitant	Tablet	Unknown				
NOVORAPID	Concomitant	SOLUTION SUBCUTANEOUS	Unknown				
PANTOPRAZOLE MAGNESIUM	Concomitant	Tablets	Unknown				
PERINDOPRIL ERBUMINE	Concomitant	Tablets	Unknown				
ROSUVASTATIN CALCIUM	Concomitant	Tablet	Unknown				
TOPIRAMATE	Concomitant	NOT SPECIFIED	Unknown				
VENTOLIN	Concomitant	NOT SPECIFIED	Unknown				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Erythema	v.24.1	
Fatigue	v.24.1	
Pruritus	v.24.1	
Pyrexia	v.24.1	
Swelling	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:08:27 AM
Initial Received Date:	2021-07-30 to 2021-09-30
Latest Received Date:	N/A
Total Number of Reports:	703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04531039	1	2021-08-10	2021-09-09	MAH	2021A674551	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
55 Years	Male	185 Centimeter	89 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.5 ml			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bone pain	v.24.1	
Malaise	v.24.1	
Myalgia	v.24.1	
Pain in extremity	v.24.1	
Paraesthesia	v.24.1	
Peripheral swelling	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Thrombophlebitis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04531306	1	2021-08-10	2021-09-10	MAH	2021A674545	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
56 Years	Female		60 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Prophylaxis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypothyroidism	v.24.1	
Tachycardia	v.24.1	
Weight decreased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04531410	1	2021-08-10	2021-09-13	MAH	2021A674466	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
57 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intravenous (not otherwise specified)				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Back pain	v.24.1	
Chills	v.24.1	
Incorrect route of product administration	v.24.1	
Movement disorder	v.24.1	
Pyrexia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04531418	1	2021-08-10	2021-09-08	MAH	2021A674575	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
57 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anti-platelet antibody	v.24.1	
Deep vein thrombosis	v.24.1	7 Days
Fibrin D dimer increased	v.24.1	
Headache	v.24.1	
Immune thrombocytopenia	v.24.1	7 Days
Oedema peripheral	v.24.1	
Platelet count decreased	v.24.1	
Pulmonary embolism	v.24.1	7 Days

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pulmonary infarction	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04531610	0	2021-08-10	2021-08-10	MAH	202100964445	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
20 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
APO-CLOBAZAM	Concomitant	Tablets					
MYLAN DIVALPROEX	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
TOPIRAMATE	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Loss of consciousness	v.24.1	
Pyrexia	v.24.1	
Tremor	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:08:27 AM
Initial Received Date:	2021-07-30 to 2021-09-30
Latest Received Date:	N/A
Total Number of Reports:	703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04531727	0	2021-08-10	2021-08-10	MAH	2882026	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
65 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AZATHIOPRINE	Concomitant	NOT SPECIFIED					Product used for unknown indication
COVID-19 VACCINE	Suspect		Unknown				Product used for unknown indication
INSULIN	Concomitant	GLOBULES ORAL					Product used for unknown indication
LEVOTHYROXINE SODIUM	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication
METFORMIN	Concomitant	Tablet	Oral				Product used for unknown indication

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PREDNISONE	Concomitant	NOT SPECIFIED	Oral	40.0 Milligram			Product used for unknown indication
RITUXIMAB	Suspect		Intravenous drip	1000.0 Milligram		833.0 Days	Rheumatoid arthritis
ROSUVASTATIN	Concomitant	NOT SPECIFIED	Subcutaneous				Product used for unknown indication
SANDOZ IRBESARTAN	Concomitant	Tablets					Product used for unknown indication
SYNTHROID	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Arthritis	v.24.1	
C-reactive protein increased	v.24.1	
Dyspnoea exertional	v.24.1	
Eosinophil count increased	v.24.1	
Fatigue	v.24.1	
Ill-defined disorder	v.24.1	
Interstitial lung disease	v.24.1	
Joint swelling	v.24.1	
Monocyte count increased	v.24.1	
Red blood cell sedimentation rate increased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04531997	0	2021-08-10	2021-08-10	MAH	2021A674664	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
68 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.24.1	
Diarrhoea	v.24.1	
Dizziness	v.24.1	
Fatigue	v.24.1	
Flushing	v.24.1	
Headache	v.24.1	
Hypoaesthesia	v.24.1	
Injection site erythema	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Injection site pain	v.24.1	
Injection site swelling	v.24.1	
Nausea	v.24.1	
Paraesthesia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04532150	0	2021-08-10	2021-08-10	MAH	202100993208	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
61 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_04542392

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Eczema	v.24.1	
Fatigue	v.24.1	
Feeling hot	v.24.1	
Helicobacter infection	v.24.1	27 Days
Pruritus	v.24.1	
Rash	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Rash morbilliform	v.24.1	
Thirst	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04532152	0	2021-08-10	2021-08-10	MAH	202100993185	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
45 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blindness unilateral	v.24.1	
Fatigue	v.24.1	
Inappropriate schedule of product administration	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04532162	0	2021-08-10	2021-08-10	MAH	202100963191	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
51 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Haemorrhage	v.24.1	0 Months

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04532163	0	2021-08-10	2021-08-10	MAH	202100955978	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
41 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	
Headache	v.24.1	
Oropharyngeal pain	v.24.1	48 Hours

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04532169	0	2021-08-10	2021-08-10	MAH	202100958266	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
31 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cardiac flutter	v.24.1	
Discomfort	v.24.1	
Fatigue	v.24.1	
Headache	v.24.1	
Heavy menstrual bleeding	v.24.1	
Inappropriate schedule of product administration	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Lymphadenopathy	v.24.1	
Menstruation irregular	v.24.1	
Musculoskeletal chest pain	v.24.1	
Oropharyngeal pain	v.24.1	
Palpitations	v.24.1	
Rash erythematous	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04532179	0	2021-08-10	2021-08-10	MAH	202100962882	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
31 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
DOXYCYCLINE	Concomitant	NOT SPECIFIED		100.0 Milligram			
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Heart rate increased	v.24.1	-175
Immobile	v.24.1	-175
Malaise	v.24.1	-175
Pain	v.24.1	2 Hours
Pyrexia	v.24.1	2 Hours

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04532180	1	2021-08-10	2021-09-13	MAH	202100957194	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
66 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
LOMOTIL [LOPERAMIDE HYDROCHLORIDE]	Concomitant		Oral				Diarrhoea
LORAZEPAM	Concomitant	NOT SPECIFIED	Oral				Anxiety
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
SERTRALINE	Concomitant	Capsules					
SERTRALINE HYDROCHLORIDE	Concomitant		Oral				Anxiety
SYNTHROID	Concomitant	NOT SPECIFIED	Oral				Hypothyroidism
TERAZOSIN HYDROCHLORIDE	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Groin pain	v.24.1	
Mobility decreased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04532187	0	2021-08-10	2021-08-10	MAH	202100993103	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
42 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
VENLAFAXINE HYDROCHLORIDE	Concomitant		Oral				Depression

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypoaesthesia	v.24.1	
Multiple sclerosis relapse	v.24.1	
Paraesthesia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:08:27 AM
Initial Received Date:	2021-07-30 to 2021-09-30
Latest Received Date:	N/A
Total Number of Reports:	703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04533259	0	2021-08-10	2021-08-10	MAH	202100975698	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
70 Years	Female			Recovered/resolved with sequelae

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cardiac arrest	v.24.1	1 Months
Cardiac failure	v.24.1	1 Months
Dyspnoea	v.24.1	1 Months
Inappropriate schedule of product administration	v.24.1	
Palpitations	v.24.1	1 Months

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:08:27 AM
Initial Received Date:	2021-07-30 to 2021-09-30
Latest Received Date:	N/A
Total Number of Reports:	703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04533563	0	2021-08-10	2021-08-10	MAH	202100962705	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
22 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular			1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.24.1	10 Days
Fatigue	v.24.1	
Head discomfort	v.24.1	10 Days
Heart rate increased	v.24.1	
Hypoaesthesia	v.24.1	
Insomnia	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Joint stiffness	v.24.1	
Keratitis	v.24.1	
Neck pain	v.24.1	
Tinnitus	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04534116	1	2021-08-11	2021-09-08	MAH	2021A674640	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
57 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Subcutaneous	0.5 ml			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.24.1	
Dyspnoea	v.24.1	
Incorrect route of product administration	v.24.1	
Intracranial aneurysm	v.24.1	
Oedema peripheral	v.24.1	
Pain in extremity	v.24.1	
Pulmonary embolism	v.24.1	
Pulmonary infarction	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Thrombocytopenia	v.24.1	
Thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:08:27 AM
Initial Received Date:	2021-07-30 to 2021-09-30
Latest Received Date:	N/A
Total Number of Reports:	703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04534476	1	2021-08-11	2021-09-10	MAH	2021A674642	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
59 Years	Male	173 Centimeter	103 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETAMINOPHEN	Concomitant	NOT SPECIFIED	Unknown				
ALLOPURINOL	Concomitant	Tablets	Unknown				
AMLODIPINE MESYLATE	Concomitant	Tablet	Unknown	10.0 Milligram			
ASA	Concomitant	NOT SPECIFIED	Unknown	81.0 Milligram			
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.5 ml			Immunisation
CALCIUM	Concomitant	NOT SPECIFIED	Unknown				
COBAMAMIDE	Concomitant	Tablet	Unknown				
CYMBALTA	Concomitant	NOT SPECIFIED	Unknown				
ERENUMAB AOOE	Concomitant		Subcutaneous				
ERGOCALCIFEROL	Concomitant		Unknown				
ERYTHROMYCIN PROPIONATE	Concomitant		Unknown				

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
FERROUS FUMARATE	Concomitant	NOT SPECIFIED	Unknown	300.0 Milligram			
LINAGLIPTIN	Concomitant						
LIPITOR	Concomitant	NOT SPECIFIED	Unknown				
MOXIFLOXACIN HYDROCHLORIDE	Concomitant		Unknown				
PANTOPRAZOLE SODIUM	Concomitant		Intracavernous				
PENICILLIN G POTASSIUM	Concomitant		Unknown				
PREGABALIN	Concomitant	Capsules	Unknown				
VALPROATE SEMISODIUM	Concomitant		Unknown				
VENTOLIN	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Heart rate increased	v.24.1	
Pallor	v.24.1	
Paraesthesia oral	v.24.1	
Pharyngeal paraesthesia	v.24.1	
Tremor	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04534483	1	2021-08-11	2021-09-09	MAH	2021A674541	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.5 ml			Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	
Headache	v.24.1	
Pyrexia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04534786	1	2021-08-11	2021-09-07	MAH	2021A674645	Spontaneous	Physician

Serious report?	Death:	Yes	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
48 Years	Female	170 Centimeter	80 Kilogram	Fatal

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Immunisation
DULOXETINE HYDROCHLORIDE	Concomitant		Unknown				
FLOVENT HFA	Concomitant	METERED-DOSE (AEROSOL)	Unknown				
FLURAZEPAM HYDROCHLORIDE	Concomitant	Capsules	Unknown				
LEVOMEPROMAZINE MALEATE	Concomitant		Unknown				
LEVOTHYROXINE SODIUM	Concomitant	NOT SPECIFIED	Unknown				
MELATONIN	Concomitant	NOT SPECIFIED	Unknown				
NABILONE	Concomitant		Unknown				

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ONDANSETRON HYDROCHLORIDE	Concomitant	Tablet	Unknown				
PMS RABEPRAZOLE EC	Concomitant	Tablet	Unknown				
PREGABALIN	Concomitant	Capsules	Unknown				
RANITIDINE HYDROCHLORIDE	Concomitant	Tablet	Unknown				
SALBUTAMOL	Concomitant	NOT SPECIFIED	Unknown				
SANDOZ DICLOFENAC	Concomitant	Suppository	Unknown				
TEVA FENTANYL	Concomitant	Transdermal patch	Unknown				
TRAZODONE	Concomitant	Tablets	Unknown				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.24.1	
Nausea	v.24.1	
Somnolence	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04534836	0	2021-08-11	2021-08-11	MAH	2021A674533	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Injection site mass	v.24.1	
Pain in extremity	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04534871	1	2021-08-11	2021-09-13	MAH	2021A674524	Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
67 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.5 ml			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blister	v.24.1	
Pigmentation disorder	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04534961	1	2021-08-11	2021-09-08	MAH	2021A674579	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
55 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.24.1	
Night sweats	v.24.1	
Tinnitus	v.24.1	
Vertigo	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04535289	1	2021-08-11	2021-09-14	MAH	2021A674549	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
53 Years	Female	160 Centimeter	74 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.5 ml			Prophylaxis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dry mouth	v.24.1	
Dysphagia	v.24.1	
Muscle tightness	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04535653	0	2021-08-11	2021-08-11	MAH	MOD-2021-270198	Published	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
56 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CICLOSPORIN	Concomitant	NOT SPECIFIED	Unknown	75.0 Milligram	1 every 1 Days		Immunosuppression
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	1.0 Dosage forms			COVID-19 immunisation
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	Injection	Intramuscular	1.0 Dosage forms			COVID-19 immunisation
MYCOPHENOLATE SODIUM	Concomitant		Unknown	900.0 Milligram	2 every 1 Days		Immunosuppression
PREDNISONE	Concomitant	NOT SPECIFIED	Unknown	10.0 Milligram	1 every 1 Days		Immunosuppression

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.24.1	
Drug ineffective	v.24.1	
Fatigue	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04535845	0	2021-08-11	2021-08-11	MAH	CA2021AMR168266	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
87 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				Prophylaxis
MEPOLIZUMAB	Suspect		Subcutaneous	100.0 Milligram			Asthma

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Myocardial infarction	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04535955	0	2021-08-11	2021-08-11	MAH	2021A665653	Published	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
71 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Product used for unknown indication
ROSUVASTATIN	Concomitant	NOT SPECIFIED	Unknown	20.0 Milligram	1 every 1 Days		Dyslipidaemia

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Glomerulonephritis minimal lesion	v.24.1	
Hypertension	v.24.1	
Renal tubular injury	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04536257	0	2021-08-11	2021-08-11	MAH	2021640196	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
40 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.24.1	
Heart rate increased	v.24.1	
Palpitations	v.24.1	
Pyrexia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04536267	0	2021-08-11	2021-08-11	MAH	2021664691	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
54 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular			34.0 Hours	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blepharitis	v.24.1	
Blister	v.24.1	
Erythema	v.24.1	
Joint swelling	v.24.1	
Pemphigoid	v.24.1	
Skin disorder	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04536394	0	2021-08-11	2021-08-11	MAH	202101005276	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
38 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation
XELJANZ XR	Concomitant	TABLET (EXTENDED-RELEASE)		11.0 Milligram			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Colitis ulcerative	v.24.1	
Rheumatoid arthritis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04536496	0	2021-08-11	2021-08-11	MAH	202100956354	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
31 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CIPROFLOXACIN	Concomitant	NOT SPECIFIED		500.0 Milligram	2 every 1 Days		
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Appendicitis	v.24.1	
Inappropriate schedule of product administration	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:08:27 AM
Initial Received Date:	2021-07-30 to 2021-09-30
Latest Received Date:	N/A
Total Number of Reports:	703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04536503	2	2021-08-11	2021-09-13	MAH	202100963101	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
19 Years	Male		67 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Back injury	v.24.1	
Confusional state	v.24.1	
Decreased eye contact	v.24.1	
Disease recurrence	v.24.1	
Disease recurrence	v.24.1	
Disturbance in attention	v.24.1	6 Weeks

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Epilepsy	v.24.1	
Epilepsy	v.24.1	
Fatigue	v.24.1	6 Weeks
Lethargy	v.24.1	6 Weeks
Tonic convulsion	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04536520	0	2021-08-11	2021-08-11	MAH	202101005399	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
78 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MRNA-1273 SARS-COV-2	Suspect	NOT SPECIFIED	Unknown		Total		COVID-19 immunisation
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Foot fracture	v.24.1	
Spinal stenosis	v.24.1	
Wrong product administered	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04536569	0	2021-08-11	2021-08-11	MAH	202100975728	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
42 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
DESOGESTREL/ETHINYL ESTRADIOL	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
SYNTHROID	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Diastolic hypertension	v.24.1	
Inappropriate schedule of product administration	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04536586	0	2021-08-11	2021-08-11	MAH	202100970057	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
16 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Syncope	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04536660	0	2021-08-11	2021-08-11	MAH	202100969753	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
81 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood albumin decreased	v.24.1	
Condition aggravated	v.24.1	
Localised oedema	v.24.1	
Low density lipoprotein increased	v.24.1	
Nephrotic syndrome	v.24.1	
Oedema peripheral	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pneumonia	v.24.1	
Scrotal oedema	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04538638	0	2021-08-12	2021-08-12	MAH	2021A676213	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04538767	0	2021-08-12	2021-08-12	MAH	2021A676229	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACTEMRA	Suspect	NOT SPECIFIED	Subcutaneous				Rheumatoid arthritis
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Product used for unknown indication
BISOPROLOL	Concomitant	Tablets	Unknown				
ESCITALOPRAM OXALATE	Concomitant						
FOLIC ACID	Concomitant	NOT SPECIFIED					
JARDIANCE	Concomitant						
LEFLUNOMIDE	Concomitant	NOT SPECIFIED					
LEUCOVORIN	Concomitant	NOT SPECIFIED					
LEVOTHYROXINE SODIUM	Concomitant	NOT SPECIFIED	Unknown				
MAGNESIUM	Concomitant	NOT SPECIFIED					

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
METFORMIN HYDROCHLORIDE/SITAGLIPTIN PHOSPHATE MONOHYDRATE	Concomitant						
METHOTREXATE	Concomitant	NOT SPECIFIED	Oral				
PREDNISONE	Concomitant	NOT SPECIFIED					
PREGABALIN	Concomitant	Capsules					
RABEPRAZOLE	Concomitant	NOT SPECIFIED					
RAMIPRIL	Concomitant	NOT SPECIFIED					
RISEDRONATE	Concomitant	Tablets					
ROSUVASTATIN CALCIUM	Concomitant						
VITAMIN D3	Concomitant	Capsules					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	
Headache	v.24.1	
Pyrexia	v.24.1	
Thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04539976	0	2021-08-12	2021-08-12	MAH	2021A568673	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
32 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				COVID-19 immunisation
BETA-CAROTENE/CALCIUM SULFATE/D-ALPHA TOCOPHERYL ACETATE/FERROUS FUMARATE/FOLIC ACID/NICOTINAMIDE/PYRIDOXINE HYDROCHLORIDE/RIBOFLAVIN/THIAMINE MONONITRATE/VITAMIN A ACETATE/VITAMIN B12/VITAMIN C/VITAMIN D3/ZINC OXIDE	Concomitant						

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
TOZINAMERAN	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abortion spontaneous	v.24.1	
Chills	v.24.1	2 Days
Maternal exposure during pregnancy	v.24.1	
Myalgia	v.24.1	2 Days
Pain in extremity	v.24.1	6 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04542322	0	2021-08-12	2021-08-12	MAH	2021664312	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
4 Months				Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Transmammary				COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Diarrhoea	v.24.1	
Exposure via breast milk	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04542392	0	2021-08-12	2021-08-12	MAH	202100993247	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
61 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_04532150

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood chloride decreased	v.24.1	
Blood cholesterol increased	v.24.1	
Blood pressure increased	v.24.1	-179
Chest discomfort	v.24.1	
Dyspnoea	v.24.1	
Fatigue	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Feeling hot	v.24.1	
Haemoglobin decreased	v.24.1	
Heart rate increased	v.24.1	
Insomnia	v.24.1	
Rash	v.24.1	
Somnolence	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04542474	0	2021-08-12	2021-08-12	MAH	202100985550	Spontaneous	Other health professional

Serious report?	Death:	Disability:	Congenital Anomaly:
Serious	No	Yes	No
	Life Threatening: No	**Hospitalization:** No	**Other Medically Important Conditions:** No

Patient Information

Age	Gender	Height	Weight	Report Outcome
26 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_04542482
Linked	
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Axillary mass	v.24.1	
Axillary pain	v.24.1	
Breast mass	v.24.1	
Breast pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04542482	0	2021-08-12	2021-08-12	MAH	202100985588	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	E2B_04542474
Linked	E2B_04542630

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Axillary mass	v.24.1	
Axillary pain	v.24.1	
Breast mass	v.24.1	
Breast pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04542486	0	2021-08-12	2021-08-12	MAH	202100985690	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
53 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	
Weight decreased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04542491	1	2021-08-12	2021-08-30	MAH	202100976592	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
49 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
DESLORATADINE	Concomitant	Tablets					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Alopecia	v.24.1	
Appendicitis	v.24.1	
Arthralgia	v.24.1	
Chest pain	v.24.1	
Dizziness	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dyspnoea	v.24.1	
Fatigue	v.24.1	
Gastrooesophageal reflux disease	v.24.1	
Impaired gastric emptying	v.24.1	
Lymph node pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04542495	0	2021-08-12	2021-08-12	MAH	202100977391	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
41 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Angina pectoris	v.24.1	
Hypoaesthesia	v.24.1	
Pain in extremity	v.24.1	
Paraesthesia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:08:27 AM
Initial Received Date:	2021-07-30 to 2021-09-30
Latest Received Date:	N/A
Total Number of Reports:	703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04542542	0	2021-08-12	2021-08-12	MAH	202100975812	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
45 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
SYNTHROID	Concomitant	NOT SPECIFIED					
VITAMIN D	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Retinal artery occlusion	v.24.1	
Retinal injury	v.24.1	
Retinal vein occlusion	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04542607	0	2021-08-12	2021-08-12	MAH	202100992779	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
2 Weeks	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	E2B_05260521

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Transplacental		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypoglycaemia neonatal	v.24.1	
Hypothermia neonatal	v.24.1	
Infantile apnoea	v.24.1	
Maternal exposure during pregnancy	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04542630	0	2021-08-12	2021-08-12	MAH	202100985589	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_04542482

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Axillary mass	v.24.1	
Axillary pain	v.24.1	
Breast mass	v.24.1	
Breast pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04542854	0	2021-08-12	2021-08-12	MAH	2021A677680	Published	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
66 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Capillary leak syndrome	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04544008	1	2021-08-12	2021-09-01	MAH	2021665271	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain	v.24.1	20 Minutes
Balance disorder	v.24.1	
Chest pain	v.24.1	
Confusional state	v.24.1	24 Hours
Decreased appetite	v.24.1	
Feeling abnormal	v.24.1	24 Hours

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Memory impairment	v.24.1	24 Hours
Nausea	v.24.1	
Palpitations	v.24.1	
Pleuritic pain	v.24.1	
Tremor	v.24.1	2 Days
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04544947	0	2021-08-12	2021-08-12	MAH	202100977516	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
46 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	
Heavy menstrual bleeding	v.24.1	
Muscle twitching	v.24.1	
Postmenopausal haemorrhage	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04545882	0	2021-08-12	2021-08-12	MAH	2021764480	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
38 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Heavy menstrual bleeding	v.24.1	
Menstrual disorder	v.24.1	
Menstruation irregular	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:08:27 AM
Initial Received Date:	2021-07-30 to 2021-09-30
Latest Received Date:	N/A
Total Number of Reports:	703 Report(s)

Report Information

***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04545885	0	2021-08-12	2021-08-12	MAH	202100969655	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
26 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETYLSALICYLIC ACID	Concomitant		Oral				Pain
ARIPIPRAZOLE	Concomitant		Oral				Affective disorder
CLOBAZAM	Concomitant	Tablets	Oral				Seizure
CYANOCOBALAMIN	Concomitant		Oral				Anaemia
ELTROXIN	Concomitant	Tablets	Oral				Hypothyroidism
ESCITALOPRAM	Concomitant	Tablets	Oral				Anxiety
FOLIC ACID	Concomitant	NOT SPECIFIED	Oral				Migraine
PANTOPRAZOL [PANTOPRAZOLE]	Concomitant		Oral				Depression
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
TOPIRAMATE	Concomitant	NOT SPECIFIED	Oral				Epilepsy

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.24.1	1 Months

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04547378	0	2021-08-13	2021-08-13	MAH	MOD-2021-274725	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
32 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	1.0 Dosage forms			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Foetal death	v.24.1	
Maternal exposure during pregnancy	v.24.1	
Pain	v.24.1	
Vaginal haemorrhage	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04549163	0	2021-08-13	2021-08-13	MAH	202100992987	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
39 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Inappropriate schedule of product administration	v.24.1	
Menometrorrhagia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04549164	1	2021-08-13	2021-08-25	MAH	202100985805	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
16 Years	Male	157 Centimeter	53 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blindness	v.24.1	
Deafness	v.24.1	
Dizziness	v.24.1	
Heart rate increased	v.24.1	
Hypertension	v.24.1	
Inappropriate schedule of product administration	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Tinnitus	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04549270	0	2021-08-13	2021-08-13	MAH	202100985464	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
41 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AMLODIPINE	Concomitant	Tablets		5.0 Milligram			
CANDESARTAN 16 MG + HIDROCLOROTIAZIDA 12.5 MG	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Heavy menstrual bleeding	v.24.1	
Menometrorrhagia	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Polymenorrhoea	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04549297	1	2021-08-13	2021-09-10	MAH	202101005347	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
67 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
HYDROCHLOROTHIAZIDE/ VALSARTAN	Concomitant		Oral				Hypertelorism
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
SANDOZ AMLODIPINE [AMLODIPINE BESILATE]	Concomitant	Tablets	Oral				Hypertension

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dyspnoea	v.24.1	
Gait inability	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pain in extremity	v.24.1	
Pulmonary embolism	v.24.1	
Thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04549387	0	2021-08-13	2021-08-13	MAH	202101022518	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
65 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Appendicitis perforated	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:08:27 AM
Initial Received Date:	2021-07-30 to 2021-09-30
Latest Received Date:	N/A
Total Number of Reports:	703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04549402	1	2021-08-13	2021-09-17	MAH	202101022496	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
43 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ESCITALOPRAM	Concomitant	Tablets					
LANSOPRAZOLE	Concomitant	CAPSULE, DELAYED RELEASE					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
VITAMINS NOS	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Deep vein thrombosis	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Gait disturbance	v.24.1	
Pulmonary embolism	v.24.1	
Soft tissue infection	v.24.1	
Vaginal haemorrhage	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:08:27 AM
Initial Received Date:	2021-07-30 to 2021-09-30
Latest Received Date:	N/A
Total Number of Reports:	703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04549829	0	2021-08-13	2021-08-13	MAH	MOD-2021-276708	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
74 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ATROVAST	Concomitant		Unknown				Product used for unknown indication
CITALOPRAM	Concomitant		Unknown				Product used for unknown indication
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Unknown	1.0 Dosage forms			COVID-19 immunisation
FOLIC ACID	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
INFLIXIMAB	Suspect		Intravenous (not otherwise specified)				Rheumatoid arthritis
METFORMIN	Concomitant		Unknown				Product used for unknown indication
PANTOPRAZOLE SODIUM	Concomitant		Unknown				Product used for unknown indication
SULFASALAZINE	Concomitant	NOT SPECIFIED	Unknown				Psoriatic arthropathy
SYNTHROID	Concomitant	NOT SPECIFIED	Unknown	0.15 Milligram			Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain	v.24.1	
Asthenia	v.24.1	
Diarrhoea	v.24.1	
Headache	v.24.1	
Malaise	v.24.1	
Muscle spasms	v.24.1	
Rectal haemorrhage	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04549906	0	2021-08-13	2021-08-13	MAH	MOD-2021-276527	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
36 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	1.0 Dosage forms			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Burning sensation	v.24.1	
Skin swelling	v.24.1	
Tenderness	v.24.1	
Vaccination site joint warmth	v.24.1	
Vaccination site swelling	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04551258	0	2021-08-13	2021-08-13	MAH	MOD-2021-278174	Spontaneous	Consumer/other non health professional

Serious report?
Serious

Death:	No	**Disability:**	No	**Congenital Anomaly:**	No
Life Threatening:	No	**Hospitalization:**	Yes	**Other Medically Important Conditions:**	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
27 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Unknown	1.0 Dosage forms			COVID-19 immunisation
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	Injection	Unknown	1.0 Dosage forms			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anxiety	v.24.1	
Chest pain	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Costochondritis	v.24.1	
Dyspnoea	v.24.1	
Limb discomfort	v.24.1	
Myalgia	v.24.1	
Myocarditis	v.24.1	
Pericarditis	v.24.1	
Pyrexia	v.24.1	
Quality of life decreased	v.24.1	
Sitting disability	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04551566	1	2021-08-13	2021-08-30	MAH	202101005560	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Sensory loss	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04551664	0	2021-08-13	2021-08-13	MAH	202101022711	Study	

Serious report?	Death:	Yes	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
95 Years	Male			Fatal

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
ELIGARD	Suspect	POWDER FOR SUSPENSION, SUSTAINED-RELEASE	Subcutaneous	22.5 Milligram	1 every 3 Months		Prostate cancer

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cardiac failure congestive	v.24.1	
Dyspnoea	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04551721	0	2021-08-13	2021-08-13	MAH	2021658002	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
32 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown			1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Lymphadenopathy	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:08:27 AM
Initial Received Date:	2021-07-30 to 2021-09-30
Latest Received Date:	N/A
Total Number of Reports:	703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04551913	0	2021-08-13	2021-08-13	MAH	MOD-2021-275177	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
73 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETAMINOPHEN	Concomitant						Product used for unknown indication
ACETYLSALICYLIC ACID	Concomitant			81.0 Milligram			Product used for unknown indication
ATORVASTATIN CALCIUM	Concomitant	Tablets					Product used for unknown indication
BUDESONIDE/FORMOTEROL FUMARATE	Concomitant				2 every 1 Days		Product used for unknown indication

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	1.0 Dosage forms			COVID-19 immunisation
SALBUTAMOL	Concomitant	NOT SPECIFIED					Product used for unknown indication
TEVA-DULOXETINE	Concomitant	NOT SPECIFIED		30.0 Milligram	1 every 1 Days		Product used for unknown indication
VITAMIN D3	Concomitant				2 every 1 Days		Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Angioedema	v.24.1	
Erythema	v.24.1	
Pruritus	v.24.1	
Urticaria	v.24.1	
Urticaria	v.24.1	
Vaccination site reaction	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04553420	0	2021-08-16	2021-08-16	MAH	CA2021AMR168834	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
46 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_01611929
Linked	E2B_01323956
Linked	
Linked	
Linked	E2B_04176738
Linked	E2B_01910062
Linked	
Linked	E2B_02386018
Linked	E2B_03087395
Linked	
Linked	
Linked	E2B_03444347

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASA	Concomitant	NOT SPECIFIED	Oral	80.0 Milligram	1 every 1 Days		Product used for unknown indication

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AZITHROMYCIN	Concomitant	NOT SPECIFIED	Oral	250.0 Milligram	1 every 1 Days		Infection prophylaxis
BISOPROLOL	Concomitant		Oral	5.0 Milligram	1 every 1 Days		Product used for unknown indication
CALCIUM	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication
CLOPIDOGREL	Suspect	Tablets	Oral	75.0 Milligram	1 every 1 Days	20.0 Days	Product used for unknown indication
COVID-19 VACCINE	Suspect		Unknown				Product used for unknown indication, COVID-19 prophylaxis
COVID-19 VACCINE	Suspect		Unknown				Product used for unknown indication, COVID-19 prophylaxis
FORMOTEROL FUMARATE/MOMETASONE FUROATE	Concomitant		Unknown				Product used for unknown indication
FUROSEMIDE	Concomitant	NOT SPECIFIED	Oral	20.0 Milligram	2 every 1 Days		Product used for unknown indication
MEPOLIZUMAB	Suspect		Subcutaneous	100.0 Milligram			Asthma
MOMETASONE	Concomitant		Unknown				Product used for unknown indication
MONTELUKAST SODIUM	Concomitant		Unknown				Product used for unknown indication
OMEGA 3	Concomitant		Unknown				Product used for unknown indication
PANTOPRAZOLE	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PREGABALIN	Concomitant	Capsules	Unknown				Product used for unknown indication
SPIRONOLACTONE	Concomitant	Tablets	Oral	25.0 Milligram	1 every 1 Days		Product used for unknown indication
VALTREX	Concomitant		Unknown				Product used for unknown indication
VENTOLIN	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication
VITAMIN C	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cerebrovascular accident	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04554068	0	2021-08-16	2021-08-16	MAH	21K-028-4025148-00	Study	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
71 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	
Linked	E2B_02753181
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular			0.0	COVID-19 immunisation
COVID-19 VACCINE	Suspect		Intramuscular			1.0 Months	COVID-19 immunisation
HUMIRA	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous			9.0 Months	Crohn's disease
HUMIRA	Suspect	Solution for injection in pre-filled pen	Subcutaneous				Crohn's disease

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Adverse food reaction	v.24.1	
Arthritis	v.24.1	
Asthenopia	v.24.1	
Drug ineffective	v.24.1	
Fatigue	v.24.1	
Frequent bowel movements	v.24.1	
Gastrointestinal inflammation	v.24.1	
Inflammatory marker increased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:08:27 AM
Initial Received Date:	2021-07-30 to 2021-09-30
Latest Received Date:	N/A
Total Number of Reports:	703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04554222	0	2021-08-16	2021-08-16	MAH	20210821325	Study	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
62 Years	Female		86 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown			1.0 Days	COVID-19 prophylaxis
STELARA	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous	90.0 Milligram	1 every 8 Weeks		Colitis ulcerative

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cellulitis	v.24.1	7 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04554590	1	2021-08-16	2021-09-16	MAH	202100998924	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
57 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
ROSUVASTATIN CALCIUM	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pulmonary embolism	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04554753	1	2021-08-16	2021-08-26	MAH	202101035018	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
53 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Acute myocardial infarction	v.24.1	
Inappropriate schedule of product administration	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04555926	0	2021-08-16	2021-08-16	MAH	202100991472	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
43 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
DESVENLAFAXINE SUCCINATE	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Ear infection	v.24.1	
Glossodynia	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Lymphadenopathy	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Oropharyngeal pain	v.24.1	
Pain	v.24.1	
Tonsillar ulcer	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04556133	0	2021-08-16	2021-08-16	MAH	MOD-2021-280131	Published	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
34 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	Injection	Intramuscular	1.0 Dosage forms			COVID-19 immunisation
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	1.0 Dosage forms			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cardiac failure	v.24.1	9 Days
Chest pain	v.24.1	9 Days
Myalgia	v.24.1	9 Days
Myocarditis	v.24.1	9 Days

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pyrexia	v.24.1	9 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04556199	0	2021-08-16	2021-08-16	MAH	2021827768	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
27 Years	Female	170 Centimeter	72 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
DEXILANT	Concomitant	CAPSULE, DELAYED RELEASE	Oral			22.0 Years	Dyspepsia
OMEPRAZOLE	Concomitant		Oral				Dyspepsia
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Haemorrhage in pregnancy	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Maternal exposure before pregnancy	v.24.1	
Pain in extremity	v.24.1	16 Hours

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04556205	0	2021-08-16	2021-08-16	MAH	2021788991	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
66 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cardiac disorder	v.24.1	
Dizziness	v.24.1	
Labyrinthitis	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04556380	0	2021-08-16	2021-08-16	MAH	2021689687	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
61 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MEDROXYPROGESTERONE ACETATE	Concomitant		Oral				Menopause
PANTOPRAZOLE	Concomitant	NOT SPECIFIED	Oral				Gastric disorder
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Gait disturbance	v.24.1	
Joint swelling	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Loss of personal independence in daily activities	v.24.1	
Pain in extremity	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04557035	0	2021-08-16	2021-08-16	MAH	2021629713	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
58 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ERENUMAB AOOE	Concomitant						Migraine
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
PREDNISONE	Concomitant	NOT SPECIFIED					Sarcoidosis
TYLENOL	Concomitant	NOT SPECIFIED	Oral				Sarcoidosis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Diabetes mellitus	v.24.1	
Feeling abnormal	v.24.1	2 Weeks
Malaise	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04558070	0	2021-08-17	2021-08-17	MAH	MOD-2021-281424	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
51 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BUPROPION	Concomitant		Unknown				Product used for unknown indication
CETIRIZINE HYDROCHLORIDE	Concomitant		Unknown				Product used for unknown indication
CITALOPRAM	Concomitant		Unknown				Product used for unknown indication
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Unknown	1.0 Dosage forms			COVID-19 immunisation

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
POTASSIUM	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication
SYNTHROID	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication
TOZINAMERAN	Suspect		Intramuscular				COVID-19 immunisation
XARELTO	Concomitant	Coated tablet	Unknown				Deep vein thrombosis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Interchange of vaccine products	v.24.1	
Thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:08:27 AM
Initial Received Date:	2021-07-30 to 2021-09-30
Latest Received Date:	N/A
Total Number of Reports:	703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04558224	0	2021-08-17	2021-08-17	MAH	MOD-2021-280681	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
44 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Unknown	1.0 Dosage forms			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bell's palsy	v.24.1	
Product dose omission issue	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04559587	0	2021-08-17	2021-08-17	MAH	202101034731	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04559752	1	2021-08-17	2021-08-26	MAH	202101029465	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
13 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Immune system disorder	v.24.1	
Lip ulceration	v.24.1	
Pain	v.24.1	
Vulval ulceration	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04563055	0	2021-08-18	2021-08-18	MAH	2021A684688	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
71 Years	Male	170 Centimeter	66 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				COVID-19 immunisation
BETAHISTINE MESYLATE	Concomitant	Tablet	Unknown				
ROSUVASTATIN CALCIUM	Concomitant	Tablet	Unknown				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood creatinine increased	v.24.1	
Blood pressure increased	v.24.1	
Haemodialysis	v.24.1	
Headache	v.24.1	
Oedema	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Proteinuria	v.24.1	
Renal tubular necrosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:08:27 AM
Initial Received Date:	2021-07-30 to 2021-09-30
Latest Received Date:	N/A
Total Number of Reports:	703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04563706	2	2021-08-18	2021-09-08	MAH	20210811360	Study	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
59 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				Immunisation
SIMPONI	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous	50.0 Milligram	1 every 1 Months	342.0 Days	Rheumatoid arthritis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Drug ineffective	v.24.1	
Injection site pain	v.24.1	
Rheumatoid arthritis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04564251	0	2021-08-18	2021-08-18	MAH	202101027611	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
27 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MRNA-1273 SARS-COV-2	Suspect	NOT SPECIFIED	Unknown		Total		COVID-19 immunisation
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Heavy menstrual bleeding	v.24.1	
Muscle spasms	v.24.1	
Wrong product administered	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04564789	0	2021-08-18	2021-08-18	MAH	202101022578	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
35 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Heavy menstrual bleeding	v.24.1	
Menstruation irregular	v.24.1	
Polymenorrhoea	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04566404	0	2021-08-18	2021-08-18	MAH	202101040118	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
41 Years	Female			Recovered/resolved with sequelae

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
PULMICORT	Concomitant	NOT SPECIFIED		200.0 Microgram			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthma	v.24.1	
Hypersensitivity	v.24.1	
Pharyngeal swelling	v.24.1	
Polymenorrhoea	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Rhinorrhoea	v.24.1	
Swelling face	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:08:27 AM
Initial Received Date:	2021-07-30 to 2021-09-30
Latest Received Date:	N/A
Total Number of Reports:	703 Report(s)

Report Information

***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04566430	1	2021-08-18	2021-09-06	MAH	2021A686844	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
50 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				COVID-19 immunisation
PREDNISONE	Concomitant	NOT SPECIFIED	Unknown				
SOLIRIS SINGLE USE, 300 MG/30ML	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)				Neuromyelitis optica spectrum disorder

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Depression	v.24.1	
Fatigue	v.24.1	
Feeling abnormal	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.24.1	
Multiple fractures	v.24.1	
Musculoskeletal stiffness	v.24.1	
Pain in extremity	v.24.1	
Pelvic fracture	v.24.1	
Upper limb fracture	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04566532	0	2021-08-18	2021-08-18	MAH	2021576624	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
HYDROXYZINE	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
PREDNISONE	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Arthralgia	v.24.1	
Gait disturbance	v.24.1	
Insomnia	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Joint swelling	v.24.1	
Joint swelling	v.24.1	
Monoplegia	v.24.1	
Musculoskeletal stiffness	v.24.1	
Myalgia	v.24.1	
Myalgia	v.24.1	
Neck pain	v.24.1	
Pain	v.24.1	
Pain	v.24.1	
Pain in extremity	v.24.1	
Paraesthesia	v.24.1	
Peripheral swelling	v.24.1	
Peripheral swelling	v.24.1	
Pulmonary pain	v.24.1	
Swelling	v.24.1	
Swelling	v.24.1	
Vaccination site pain	v.24.1	
Vaccination site swelling	v.24.1	
Vaccination site warmth	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04566867	1	2021-08-19	2021-09-06	MAH	2021A684759	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
87 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Product used for unknown indication
ENBREL	Suspect		Subcutaneous	50.0 Milligram			Psoriatic arthropathy

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cardiac failure congestive	v.24.1	
Dementia	v.24.1	
Illness	v.24.1	
Liver disorder	v.24.1	
Pulmonary oedema	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Renal disorder	v.24.1	
Urinary tract infection	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04566868	0	2021-08-19	2021-08-19	MAH	MOD-2021-282630	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CANDESARTAN	Concomitant						Product used for unknown indication
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Unknown	1.0 Dosage forms			COVID-19 immunisation
FAMPYRA	Concomitant	TABLET (EXTENDED-RELEASE)					Product used for unknown indication
OCRELIZUMAB	Concomitant						Product used for unknown indication
TOZINAMERAN	Suspect		Unknown	1.0 Dosage forms			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	
Gait disturbance	v.24.1	
Immobile	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Interchange of vaccine products	v.24.1	
Walking aid user	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:08:27 AM
Initial Received Date:	2021-07-30 to 2021-09-30
Latest Received Date:	N/A
Total Number of Reports:	703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04567117	1	2021-08-19	2021-09-06	MAH	2021A686865	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Unknown				Product used for unknown indication
STELARA	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Influenza like illness	v.24.1	
Malaise	v.24.1	
Myalgia	v.24.1	
Nephrolithiasis	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Sinus congestion	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:08:27 AM
Initial Received Date:	2021-07-30 to 2021-09-30
Latest Received Date:	N/A
Total Number of Reports:	703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04567208	1	2021-08-19	2021-09-08	MAH	2021A684785	Study	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
78 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETYLSALICYLIC ACID	Concomitant	NOT SPECIFIED	Unknown				
ALLOPURINOL	Concomitant	Tablets	Unknown				
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Product used for unknown indication
CANDESARTAN	Concomitant		Unknown				
ESBRIET	Suspect	Tablet	Oral	801.0 Milligram	3 every 1 Days		Idiopathic pulmonary fibrosis
ESBRIET	Suspect	Tablet	Oral	534.0 Milligram	3 every 1 Days		Idiopathic pulmonary fibrosis

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ESBRIET	Suspect	Capsules	Oral	801.0 Milligram	3 every 1 Days	1.0 Years	Idiopathic pulmonary fibrosis
ESBRIET	Suspect	Tablet	Oral	801.0 Milligram	3 every 1 Days	306.0 Days	Idiopathic pulmonary fibrosis
ESBRIET	Suspect		Oral	534.0 Milligram	3 every 1 Days		Idiopathic pulmonary fibrosis
ESBRIET	Suspect		Oral	267.0 Milligram	3 every 1 Days	1.0 Months	Idiopathic pulmonary fibrosis
ESBRIET	Suspect	Capsules	Oral	534.0 Milligram	3 every 1 Days	1.0 Days	Idiopathic pulmonary fibrosis
ESBRIET	Suspect	Tablet	Oral	801.0 Milligram	3 every 1 Days		Idiopathic pulmonary fibrosis
LIPITOR	Concomitant	NOT SPECIFIED	Unknown				
METFORMIN HYDROCHLORIDE/SITAGLIPTIN PHOSPHATE MONOHYDRATE	Concomitant		Unknown				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal discomfort	v.24.1	
Arterial occlusive disease	v.24.1	
Dyspnoea	v.24.1	
Urine flow decreased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:08:27 AM
Initial Received Date:	2021-07-30 to 2021-09-30
Latest Received Date:	N/A
Total Number of Reports:	703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04567305	0	2021-08-19	2021-08-19	MAH	2889561	Study	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
46 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_04401974
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ARANESP	Concomitant	SOLUTION INTRAVENOUS					
BENADRYL	Concomitant	NOT SPECIFIED	Oral	50.0 Milligram			
CALCIUM	Concomitant	NOT SPECIFIED					
COVID-19 VACCINE	Suspect		Unknown				Product used for unknown indication
IRBESARTAN	Concomitant	Tablets	Unknown				
PREDNISONE	Concomitant	NOT SPECIFIED					
RENVELA	Concomitant	POWDER FOR SUSPENSION ORAL					

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
RITUXIMAB	Suspect	Solution for infusion	Intravenous (not otherwise specified)				Anti-neutrophil cytoplasmic antibody positive vasculitis
RITUXIMAB	Suspect		Intravenous (not otherwise specified)	500.0 Milligram			Anti-neutrophil cytoplasmic antibody positive vasculitis
SOLU-MEDROL	Concomitant	NOT SPECIFIED	Intravenous (not otherwise specified)	100.0 Milligram			
TOZINAMERAN	Concomitant						
TYLENOL	Concomitant	NOT SPECIFIED	Oral	650.0 Milligram			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Intestinal haemorrhage	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04567497	1	2021-08-19	2021-09-07	MAH	2021A684752	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
66 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular			1.0 Months	COVID-19 immunisation
HUMIRA	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous	40.0 Milligram	1 every 2 Weeks	4.0 Years	Psoriatic arthropathy
HUMIRA	Suspect	Solution for injection in pre-filled pen	Subcutaneous				Psoriatic arthropathy

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pain	v.24.1	
Pneumonia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04567659	0	2021-08-19	2021-08-19	MAH	202101005178	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
38 Years				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
IBUPROFEN	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Syncope	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04568053	0	2021-08-19	2021-08-19	MAH	202101022386	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
20 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETAMINOPHEN	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain upper	v.24.1	
Dysmenorrhoea	v.24.1	
Headache	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Menstruation delayed	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04568130	1	2021-08-19	2021-09-06	MAH	2021A684749	Study	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
59 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				COVID-19 immunisation
HUMIRA	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous	40.0 Milligram	1 every 2 Weeks		Crohn's disease

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Crohn's disease	v.24.1	
Gastrointestinal scarring	v.24.1	
Headache	v.24.1	
Hypertension	v.24.1	
Large intestinal stenosis	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Malaise	v.24.1	
Small intestinal stenosis	v.24.1	
Vaccination site pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04569084	0	2021-08-19	2021-08-19	MAH	202100997998	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
37 Years	Female			Recovered/resolved with sequelae

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MAGNESIUM	Concomitant	NOT SPECIFIED					
OMEGA 3 [FISH OIL;VITAMIN E NOS]	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation
SYNTHROID	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest discomfort	v.24.1	5 Weeks
Dyspnoea	v.24.1	5 Weeks

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Extrasystoles	v.24.1	5 Weeks
Fatigue	v.24.1	
Headache	v.24.1	5 Weeks
Heavy menstrual bleeding	v.24.1	5 Weeks
Nausea	v.24.1	5 Weeks
Palpitations	v.24.1	5 Weeks
Vertigo	v.24.1	5 Weeks

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04569740	1	2021-08-19	2021-09-07	MAH	2021A686822	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
83 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_04819833

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Product used for unknown indication
ATORVASTATIN	Concomitant	Tablets	Unknown				
BACLOFEN	Concomitant	NOT SPECIFIED	Unknown				
FUROSEMIDE	Concomitant	NOT SPECIFIED	Unknown				
INDAPAMIDE/PERINDOPRIL ERBUMINE	Concomitant		Unknown				
SILIQ 2 SINGLE USE PREFILLED SYRINGES	Suspect		Subcutaneous	210.0 Milligram	1 every 2 Weeks		Psoriasis
SILIQ 2 SINGLE USE PREFILLED SYRINGES	Suspect		Subcutaneous	210.0 Milligram	1 every 1 Weeks	1.0 Months	Psoriasis

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
SILIQ 2 SINGLE USE PREFILLED SYRINGES	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous	210.0 Milligram	1 every 2 Weeks	3.0 Months	Psoriasis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthritis	v.24.1	
Fatigue	v.24.1	
Headache	v.24.1	
Infection	v.24.1	
Injection site discharge	v.24.1	
Injection site haemorrhage	v.24.1	
Injection site vesicles	v.24.1	
Limb mass	v.24.1	
Peripheral swelling	v.24.1	
Pruritus	v.24.1	
Psoriasis	v.24.1	
Psoriatic arthropathy	v.24.1	
Somnolence	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04569984	0	2021-08-19	2021-08-19	MAH	2021734194	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
36 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown			1.0 Days	COVID-19 immunisation
VITAMINS NOS	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Diarrhoea	v.24.1	
Inappropriate schedule of product administration	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04570547	0	2021-08-19	2021-08-19	MAH	202101005363	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
52 Years	Female			Recovered/resolved with sequelae

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Axillary mass	v.24.1	-184
Chills	v.24.1	-184
Chromaturia	v.24.1	-184
Dizziness	v.24.1	-184
Fatigue	v.24.1	-184
Headache	v.24.1	-184

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Inappropriate schedule of product administration	v.24.1	
Lymphadenopathy	v.24.1	-184
Mental impairment	v.24.1	-184
Middle insomnia	v.24.1	-184
Pain in extremity	v.24.1	-184
Swelling face	v.24.1	-184

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04571488	0	2021-08-19	2021-08-19	MAH	202101005337	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
37 Years	Female			Recovered/resolved with sequelae

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MAGNESIUM	Concomitant	NOT SPECIFIED					
OMEGA 3 [FISH OIL;VITAMIN E NOS]	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation
SYNTHROID	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest discomfort	v.24.1	1 Weeks
Dyspnoea	v.24.1	1 Weeks

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Extrasystoles	v.24.1	1 Weeks
Fatigue	v.24.1	1 Weeks
Headache	v.24.1	1 Weeks
Heavy menstrual bleeding	v.24.1	1 Weeks
Inappropriate schedule of product administration	v.24.1	
Nausea	v.24.1	1 Weeks
Palpitations	v.24.1	1 Weeks
Vertigo	v.24.1	1 Weeks

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04571658	0	2021-08-19	2021-08-19	MAH	2021A686447	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
57 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.5 ml			Product used for unknown indication
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Unknown				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Interchange of vaccine products	v.24.1	
Myalgia	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Off label use	v.24.1	
Postmenopausal haemorrhage	v.24.1	10 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:08:27 AM
Initial Received Date:	2021-07-30 to 2021-09-30
Latest Received Date:	N/A
Total Number of Reports:	703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04573401	1	2021-08-19	2021-09-06	MAH	2021A686872	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
73 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_04589505

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				COVID-19
ERGOCALCIFEROL	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication
FOLIC ACID	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication
OMEGA 3	Concomitant	Capsule	Unknown				Product used for unknown indication
PROPRANOLOL HYDROCHLORIDE	Concomitant		Unknown				Tremor

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
SILIQ 2 SINGLE USE PREFILLED SYRINGES	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous	210.0 Milligram	1 every 1 Weeks	15.0 Days	Psoriasis
SILIQ 2 SINGLE USE PREFILLED SYRINGES	Suspect		Subcutaneous	210.0 Milligram	1 every 1 Weeks		Psoriasis
XANTOFYL PALMITATE	Concomitant		Unknown				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Eye haemorrhage	v.24.1	
Myalgia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04573988	0	2021-08-19	2021-08-19	MAH	202101005210	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
49 Years	Female			Recovered/resolved with sequelae

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular			1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthma	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Insomnia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04574923	0	2021-08-20	2021-08-20	MAH	MOD-2021-285356	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
56 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_04575720

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CALCIUM	Concomitant	NOT SPECIFIED					Product used for unknown indication
COPAXONE	Concomitant				1 every 3 Weeks		Product used for unknown indication
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Unknown	1.0 Dosage forms			COVID-19 immunisation
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	Injection	Unknown	1.0 Dosage forms			COVID-19 immunisation

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MAGNESIUM	Concomitant	NOT SPECIFIED					Product used for unknown indication
OMEGA 3 COMPLEX [FISH OIL;VITAMIN E NOS]	Concomitant						Product used for unknown indication
SYNTHROID	Concomitant	NOT SPECIFIED					Product used for unknown indication
VITAMIN D	Concomitant						Product used for unknown indication
VITAMINS NOS	Concomitant						Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	
Headache	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Multiple sclerosis	v.24.1	
Pain	v.24.1	
Pain in extremity	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:08:27 AM
Initial Received Date:	2021-07-30 to 2021-09-30
Latest Received Date:	N/A
Total Number of Reports:	703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04577064	2	2021-08-20	2021-09-07	MAH	2021A686457	Study	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
33 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETAMINOPHEN	Concomitant	NOT SPECIFIED	Oral	975.0 Milligram			Premedication
ACYCLOVIR SODIUM	Concomitant		Oral	200.0 Milligram	1 every 12 Hours		
ALEMTUZUMAB	Suspect	SOLUTION INTRAVENOUS	Intravenous drip	12.0 Milligram	1 every 1 Days	5.0 Days	Relapsing-remitting multiple sclerosis
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Product used for unknown indication
BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE]	Concomitant		Oral	25.0 Milligram			Premedication
CETIRIZINE HYDROCHLORIDE	Concomitant		Oral	10.0 Milligram	1 every 12 Hours	5.0 Days	Premedication

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
GRAVOL	Concomitant	NOT SPECIFIED	Oral	50.0 Milligram			Premedication
METHYLPREDNISOLONE	Concomitant		Unknown			3.0 Days	Premedication
METHYLPREDNISOLONE	Concomitant		Intravenous (not otherwise specified)	1.0 Gram		5.0 Days	Premedication
OXYBUTYNIN HYDROCHLORIDE	Concomitant		Oral	5.0 Milligram	1 every 12 Hours		
PROZAC	Concomitant	NOT SPECIFIED	Oral	60.0 Milligram	1 every 1 Days		
RANITIDINE HYDROCHLORIDE	Concomitant		Oral	150.0 Milligram	1 every 12 Hours	5.0 Days	Premedication
SERTRALINE HYDROCHLORIDE	Concomitant		Unknown	100.0 Milligram			
TOVIAZ	Concomitant	TABLET (EXTENDED-RELEASE)	Unknown	5.0 Milligram			
TRAZODONE	Concomitant		Unknown	150.0 Milligram			
TRAZODONE	Concomitant	Tablets	Oral	150.0 Milligram	1 every 1 Days		
VITAMIN B COMPLEX	Concomitant		Oral				
VITAMIN D	Concomitant	NOT SPECIFIED	Oral				
VYVANSE	Concomitant	Capsules	Oral	40.0 Milligram			Fatigue

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal distension	v.24.1	
Abdominal pain	v.24.1	
Abdominal pain lower	v.24.1	
Acne	v.24.1	
Anxiety	v.24.1	
Asthenia	v.24.1	4 Days
Balance disorder	v.24.1	
Bronchitis	v.24.1	
Burning sensation	v.24.1	
Chills	v.24.1	1 Days
Dairy intolerance	v.24.1	
Decreased appetite	v.24.1	1 Days
Depression	v.24.1	
Device occlusion	v.24.1	1 Days

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Diarrhoea	v.24.1	
Dry skin	v.24.1	
Dyspnoea	v.24.1	1 Days
Dysuria	v.24.1	
Fatigue	v.24.1	4 Days
Frustration tolerance decreased	v.24.1	1 Days
Headache	v.24.1	4 Days
Hiccups	v.24.1	1 Days
Hypersomnia	v.24.1	
Hypertension	v.24.1	
Infusion site extravasation	v.24.1	1 Days
Malaise	v.24.1	
Migraine	v.24.1	4 Days
Multiple sclerosis relapse	v.24.1	
Muscle spasms	v.24.1	
Musculoskeletal stiffness	v.24.1	1 Days
Nasal congestion	v.24.1	1 Days
Nausea	v.24.1	1 Days
Neck mass	v.24.1	
Neurogenic bladder	v.24.1	
Oropharyngeal pain	v.24.1	
Pain	v.24.1	4 Days
Pain in extremity	v.24.1	
Palpitations	v.24.1	1 Days
Pruritus	v.24.1	1 Days
Pyrexia	v.24.1	1 Days
Self esteem decreased	v.24.1	
Swelling	v.24.1	
Thirst	v.24.1	1 Days
Urinary incontinence	v.24.1	
Urinary tract infection	v.24.1	
Urine abnormality	v.24.1	
Urticaria	v.24.1	1 Days
Viral infection	v.24.1	
Vomiting	v.24.1	2 Days

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
White blood cells urine positive	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04577283	0	2021-08-20	2021-08-20	MAH	202101022401	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
46 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Heavy menstrual bleeding	v.24.1	
Interchange of vaccine products	v.24.1	
Off label use	v.24.1	
Polymenorrhoea	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04577332	0	2021-08-20	2021-08-20	MAH	202101013075	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
27 Years	Male			Recovered/resolved with sequelae

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Herpes zoster	v.24.1	
Ophthalmic herpes zoster	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:08:27 AM
Initial Received Date:	2021-07-30 to 2021-09-30
Latest Received Date:	N/A
Total Number of Reports:	703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04577334	0	2021-08-20	2021-08-20	MAH	202101014228	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
37 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain	v.24.1	
Appendicitis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04577368	0	2021-08-20	2021-08-20	MAH	202101023049	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
34 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bell's palsy	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04577377	0	2021-08-20	2021-08-20	MAH	202101021880	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
37 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AMLODIPINE	Concomitant	Tablets	Unknown				
MILK THISTLE	Concomitant	NOT SPECIFIED	Unknown				
PANTOPRAZOLE	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Months	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain lower	v.24.1	-120
Asthenia	v.24.1	-120
Heavy menstrual bleeding	v.24.1	-120

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04577398	0	2021-08-20	2021-08-20	MAH	202101013733	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
50 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Angina pectoris	v.24.1	
Heart rate abnormal	v.24.1	
Insomnia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04577403	0	2021-08-20	2021-08-20	MAH	202101015728	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
70 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
HIZENTRA ALSO KNOW AS IMMUNE GLOBULIN (HUMAN). SINGLE USE VIALS	Suspect	SOLUTION SUBCUTANEOUS	Unknown	10.0 Gram	Cyclical		Immunodeficiency
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Gait inability	v.24.1	
Inflammation	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Muscle spasms	v.24.1	
Pain in extremity	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04577460	1	2021-08-20	2021-09-15	MAH	202101057411	Spontaneous	Physician

Serious report?	Death:	Disability:	Congenital Anomaly:
Serious	Yes	No	No
	Life Threatening: No	**Hospitalization:** No	**Other Medically Important Conditions:** No

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Fatal

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	E2B_04604593
Linked	E2B_04604593

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Transplacental		Total	1.0 Days	COVID-19 immunisation
RABEPRAZOLE	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Maternal exposure during pregnancy	v.24.1	
Premature baby	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04577573	0	2021-08-20	2021-08-20	MAH	202101013990	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bell's palsy	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04577592	0	2021-08-20	2021-08-20	MAH	202101013943	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
35 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bell's palsy	v.24.1	
Hypoaesthesia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:08:27 AM
Initial Received Date:	2021-07-30 to 2021-09-30
Latest Received Date:	N/A
Total Number of Reports:	703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04577598	0	2021-08-20	2021-08-20	MAH	202101022218	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
32 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
B-COMPLEX [VITAMIN B COMPLEX]	Concomitant						
FINASTERIDE	Concomitant	Tablets					
MAGNESIUM	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown			1.0 Days	COVID-19 immunisation
VYVANSE	Concomitant	Capsules					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.24.1	
Dyspnoea	v.24.1	
Fatigue	v.24.1	-217
Hypersensitivity	v.24.1	
Pericarditis	v.24.1	
Pyrexia	v.24.1	1 Months

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04577725	1	2021-08-20	2021-08-20	MAH	2021A684796	Study	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
83 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Product used for unknown indication
MEPOLIZUMAB	Suspect		Subcutaneous	100.0 Milligram			Asthma

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Constipation	v.24.1	
Pyrexia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04578642	0	2021-08-20	2021-08-20	MAH	202101014107	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
49 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bell's palsy	v.24.1	
Headache	v.24.1	
Hyperhidrosis	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Neck pain	v.24.1	
Off label use	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pain	v.24.1	
Pyrexia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04579926	0	2021-08-20	2021-08-20	MAH	202101022474	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
63 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AMLODIPINE BESILATE	Concomitant						
ASA	Concomitant	NOT SPECIFIED					
COVERSYL [PERINDOPRIL ERBUMINE]	Concomitant						
METOPROLOL	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
ROSUVASTATIN CALCIUM	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Atrial fibrillation	v.24.1	
Inappropriate schedule of product administration	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:08:27 AM
Initial Received Date:	2021-07-30 to 2021-09-30
Latest Received Date:	N/A
Total Number of Reports:	703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04580612	0	2021-08-20	2021-08-20	MAH	2021746762	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CYMBALTA	Concomitant	NOT SPECIFIED	Oral				Pain
GABAPENTIN	Concomitant	NOT SPECIFIED	Oral				Restless legs syndrome
METFORMIN	Concomitant		Oral				Type 2 diabetes mellitus
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
ROSUVASTATIN	Concomitant	NOT SPECIFIED	Oral				Blood cholesterol increased
SYNTHROID	Concomitant	NOT SPECIFIED	Oral				Hypothyroidism

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain	v.24.1	
Disease recurrence	v.24.1	
Herpes zoster	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Pain in extremity	v.24.1	1 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04581147	0	2021-08-23	2021-08-23	MAH	MOD-2021-286567	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	1.0 Dosage forms			COVID-19 immunisation
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	Injection	Intramuscular	1.0 Dosage forms			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Postmenopausal haemorrhage	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04581654	0	2021-08-23	2021-08-23	MAH	MOD-2021-286706	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
38 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Unknown	1.0 Dosage forms			COVID-19 immunisation
METHOTREXATE	Suspect		Unknown				Polymyositis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Liver disorder	v.24.1	
Polymyositis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04581846	0	2021-08-23	2021-08-23	MAH	MOD-2021-287068	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AVONEX	Concomitant	POWDER FOR SOLUTION INTRAMUSCULAR	Unknown				Multiple sclerosis
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	1.0 Dosage forms			COVID-19 immunisation
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	Injection	Intramuscular	1.0 Dosage forms			COVID-19 immunisation
FINGOLIMOD HYDROCHLORIDE	Concomitant		Unknown				Multiple sclerosis
OCRELIZUMAB	Concomitant		Unknown				Multiple sclerosis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	4 Days
Balance disorder	v.24.1	4 Days
Feeling abnormal	v.24.1	4 Days
Feeling of body temperature change	v.24.1	1 Months
Feeling of body temperature change	v.24.1	1 Months
Gait inability	v.24.1	4 Days
Immobile	v.24.1	1 Months
Muscular weakness	v.24.1	1 Months

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04582010	0	2021-08-23	2021-08-23	MAH	21K-028-4043035-00	Study	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
63 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular			0.0	COVID-19 immunisation
RINVOQ	Suspect	TABLET (EXTENDED-RELEASE)	Oral	15.0 Milligram	1 every 1 Days		Rheumatoid arthritis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Rheumatoid arthritis	v.24.1	
Therapeutic product effect decreased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04582858	1	2021-08-21	2021-09-06	MAH	2021A686400	Study	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
57 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETAMINOPHEN	Concomitant	NOT SPECIFIED	Oral	975.0 Milligram			Premedication
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				COVID-19
FABRAZYME	Suspect		Intravenous drip	85.0 Milligram	1 every 2 Weeks		Fabry's disease
FABRAZYME	Suspect	POWDER FOR SOLUTION INTRAVENOUS	Intravenous drip	80.0 Milligram	1 every 2 Weeks		Fabry's disease
METOPROLOL	Concomitant		Unknown				
VITAMIN D	Concomitant	NOT SPECIFIED	Unknown				
VITAMIN D	Concomitant		Unknown				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arrhythmia	v.24.1	1 Days
Asthenia	v.24.1	
Atrial fibrillation	v.24.1	3 Years
Cardiac disorder	v.24.1	
Chest discomfort	v.24.1	11 Days
Fatigue	v.24.1	
Heart rate increased	v.24.1	2 Days
Heart rate irregular	v.24.1	
Limb discomfort	v.24.1	
Pain	v.24.1	11 Days
Pain in extremity	v.24.1	11 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:08:27 AM
Initial Received Date:	2021-07-30 to 2021-09-30
Latest Received Date:	N/A
Total Number of Reports:	703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04583198	1	2021-08-23	2021-09-06	MAH	2021A684761	Study	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
44 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Duplicate	E2B_03615525

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				COVID-19 immunisation
IMMUNOGLOBULIN (HUMAN)	Suspect		Subcutaneous				Primary immunodeficiency syndrome
IMMUNOGLOBULIN (HUMAN)	Suspect	Solution for infusion	Subcutaneous				Primary immunodeficiency syndrome
IMMUNOGLOBULIN (HUMAN)	Suspect	Solution for infusion	Unknown				Primary immunodeficiency syndrome
IRON	Concomitant		Unknown				Product used for unknown indication

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
RANITIDINE	Concomitant		Unknown				
RUPATADINE FUMARATE	Concomitant		Unknown				
SINGULAIR	Concomitant	NOT SPECIFIED	Unknown				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood pressure increased	v.24.1	
Chills	v.24.1	
Fatigue	v.24.1	
Infusion site bruising	v.24.1	
Infusion site haemorrhage	v.24.1	
Infusion site pain	v.24.1	
Infusion site swelling	v.24.1	
Malaise	v.24.1	
Mastocytosis	v.24.1	
Nausea	v.24.1	
Nervous system disorder	v.24.1	
Pulmonary embolism	v.24.1	
Sinusitis	v.24.1	
Tachycardia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04584397	0	2021-08-23	2021-08-23	MAH	202101029488	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
29 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
SERTRALINE	Concomitant	Capsules					
WELLBUTRIN	Concomitant	TABLET (EXTENDED-RELEASE)					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Generalised tonic-clonic seizure	v.24.1	
Inappropriate schedule of product administration	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04584507	0	2021-08-23	2021-08-23	MAH	202101029497	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
24 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hemiparesis	v.24.1	
Hypoaesthesia	v.24.1	
Inappropriate schedule of product administration	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:08:27 AM
Initial Received Date:	2021-07-30 to 2021-09-30
Latest Received Date:	N/A
Total Number of Reports:	703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04584637	1	2021-08-23	2021-09-01	MAH	202101033495	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
37 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BIOTIN/CALCIUM CARBONATE/CALCIUM D-PANTOTHENATE/CHROMIUM NICOTINATE/CUPRIC OXIDE/D-ALPHA TOCOPHERYL ACETATE/FERROUS FUMARATE/FOLIC ACID/MAGNESIUM HYDROXIDE/MANGANESE GLUCONATE/NICOTINAMIDE/POTASSIUM IODIDE/PYRIDOXINE HYDROCHLORIDE/RIBOFLAVIN	Concomitant						
CBD COMPLEX	Concomitant						

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CYANOCOBALAMIN	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown			1.0 Days	COVID-19 immunisation
VITAMIN D	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bell's palsy	v.24.1	
Dizziness	v.24.1	
Feeling abnormal	v.24.1	
Hypoaesthesia	v.24.1	
Pain of skin	v.24.1	
Sensitive skin	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04585178	0	2021-08-23	2021-08-23	MAH	2021815106	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
51 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Postmenopausal haemorrhage	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04586024	0	2021-08-23	2021-08-23	MAH	202101022930	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
69 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
RINVOQ	Suspect	TABLET (EXTENDED-RELEASE)	Oral	15.0 Milligram	1 every 1 Days		Rheumatoid arthritis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Blood test abnormal	v.24.1	
Drug ineffective	v.24.1	
Gait disturbance	v.24.1	
Pain	v.24.1	
Pain in extremity	v.24.1	
Rheumatoid arthritis	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Suspected COVID-19	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04586310	0	2021-08-23	2021-08-23	MAH	202101022935	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
83 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ATORVASTATIN	Concomitant	Tablets	Unknown		Cyclical		
BACLOFEN	Concomitant	NOT SPECIFIED	Unknown				
BRODALUMAB	Suspect		Subcutaneous	210.0 Milligram	Cyclical	92.0 Days	Psoriasis
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
FUROSEMIDE	Concomitant	NOT SPECIFIED	Unknown				
INDAPAMIDE;PERINDOPRIL ERBUMINE	Concomitant		Unknown				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthritis	v.24.1	
Fatigue	v.24.1	
Headache	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Infection	v.24.1	
Limb mass	v.24.1	
Peripheral swelling	v.24.1	
Pruritus	v.24.1	
Psoriasis	v.24.1	
Psoriatic arthropathy	v.24.1	
Somnolence	v.24.1	
Vaccination site discharge	v.24.1	
Vaccination site haemorrhage	v.24.1	
Vaccination site vesicles	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04586624	0	2021-08-24	2021-08-24	MAH	EU-2021-02662	Study	

Serious report?	Death:	Disability:	Congenital Anomaly:
Serious	Yes	No	No
	Life Threatening: No	**Hospitalization:** Yes	**Other Medically Important Conditions:** No

Patient Information

Age	Gender	Height	Weight	Report Outcome
70 Years	Male	159 Centimeter	63 Kilogram	Fatal

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect						Product used for unknown indication
LONSURF	Suspect	Tablets	Oral				Colorectal cancer metastatic

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pneumonia	v.24.1	1 Months

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04586649	1	2021-08-24	2021-09-03	MAH	2021A686845	Study	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				COVID-19 immunisation
ORENCIA	Suspect		Subcutaneous	125.0 Milligram	1 every 1 Weeks		Rheumatoid arthritis
STELARA	Suspect	SOLUTION SUBCUTANEOUS	Unknown				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	2 Days
Atrial fibrillation	v.24.1	2 Days

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Back pain	v.24.1	2 Days
Musculoskeletal stiffness	v.24.1	2 Days
Pain in extremity	v.24.1	2 Days
Vitamin B12 decreased	v.24.1	2 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04586700	1	2021-08-24	2021-09-06	MAH	2021A684821	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
74 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				COVID-19 immunisation
HUMIRA	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous	40.0 Milligram	1 every 1 Weeks		Crohn's disease

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bacteraemia	v.24.1	
Dyspnoea	v.24.1	1 Days
Headache	v.24.1	
Pyrexia	v.24.1	1 Days
Tremor	v.24.1	1 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04587510	1	2021-08-24	2021-09-06	MAH	2021A684766	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
76 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_04595171

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACTEMRA	Suspect	NOT SPECIFIED	Subcutaneous	162.0 Milligram	1 every 1 Weeks		Rheumatoid arthritis
ACTEMRA	Suspect		Subcutaneous	162.0 Milligram	1 every 2 Weeks		Rheumatoid arthritis
ACTEMRA	Suspect		Subcutaneous	162.0 Milligram	1 every 1 Weeks	288.0 Days	Rheumatoid arthritis
ACTEMRA	Suspect		Subcutaneous	162.0 Milligram	1 every 2 Weeks		Rheumatoid arthritis
ACTEMRA	Suspect		Subcutaneous	162.0 Milligram	1 every 2 Weeks	71.0 Days	Rheumatoid arthritis
ACTEMRA	Suspect		Subcutaneous	162.0 Milligram	1 every 2 Weeks		Rheumatoid arthritis

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ALENDRONATE SODIUM	Concomitant		Unknown				Product used for unknown indication
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Product used for unknown indication
BISOPROLOL	Suspect	Tablets	Unknown				Product used for unknown indication
METHOTREXATE	Suspect	NOT SPECIFIED	Unknown				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal discomfort	v.24.1	
Abdominal tenderness	v.24.1	
Acne	v.24.1	
Arthralgia	v.24.1	
Asthenia	v.24.1	
Blood pressure increased	v.24.1	
Blood pressure systolic increased	v.24.1	
Cold sweat	v.24.1	
Cough	v.24.1	
Dermatitis	v.24.1	
Diarrhoea	v.24.1	
Dizziness	v.24.1	
Drug ineffective	v.24.1	
Drug ineffective	v.24.1	
Dry skin	v.24.1	
Fatigue	v.24.1	
Headache	v.24.1	
Heart rate increased	v.24.1	
Heart rate irregular	v.24.1	
Hypersensitivity	v.24.1	
Hypertension	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Injection site haemorrhage	v.24.1	
Injection site pain	v.24.1	
Malaise	v.24.1	
Medication error	v.24.1	
Migraine	v.24.1	
Musculoskeletal stiffness	v.24.1	
Nasopharyngitis	v.24.1	
Oropharyngeal pain	v.24.1	
Oxygen saturation decreased	v.24.1	
Pain in extremity	v.24.1	
Panic attack	v.24.1	
Rheumatoid arthritis	v.24.1	
Stress	v.24.1	
Tremor	v.24.1	
Wheezing	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04587649	1	2021-08-24	2021-09-06	MAH	CA2021AMR177132	Study	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				COVID-19 prophylaxis
MEPOLIZUMAB	Suspect		Subcutaneous	100.0 Milligram			Asthma

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthma	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Product dose omission issue	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04587834	1	2021-08-24	2021-09-14	MAH	MOD-2021-281284	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
35 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	Injection	Intramuscular	1.0 Dosage forms			COVID-19 immunisation
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	1.0 Dosage forms			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Decreased appetite	v.24.1	
Dehydration	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Diarrhoea	v.24.1	
Eye colour change	v.24.1	
Inappropriate schedule of product administration	v.24.1	1 Days
Loss of consciousness	v.24.1	
Vaccination complication	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04588375	1	2021-08-24	2021-09-21	MAH	20210630339	Study	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
65 Years	Male		79 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	
Linked	
Linked	E2B_04799781
Linked	E2B_04799781
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				COVID-19 prophylaxis
STELARA	Suspect	Solution for injection in pre-filled syringe	Subcutaneous	90.0 Milligram	1 every 4 Weeks		Crohn's disease
STELARA	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous	90.0 Milligram	1 every 8 Weeks		Crohn's disease

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Crohn's disease	v.24.1	
Drug ineffective	v.24.1	
Fall	v.24.1	
Off label use	v.24.1	
Product use issue	v.24.1	
Rib fracture	v.24.1	
Salmonellosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:08:27 AM
Initial Received Date:	2021-07-30 to 2021-09-30
Latest Received Date:	N/A
Total Number of Reports:	703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04588479	0	2021-08-24	2021-08-24	MAH	21K-028-4046165-00	Study	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
45 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular			1.0 Months	COVID-19 prophylaxis
HUMIRA	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous	40.0 Milligram	1 every 2 Weeks		Rheumatoid arthritis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Drug interaction	v.24.1	
Hypersensitivity	v.24.1	
Malaise	v.24.1	
Myocardial infarction	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04589005	5	2021-08-24	2021-12-21	MAH	MYERS SQUIBB COMPANY	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
49 Years	Female		93 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_04106384
Linked	E2B_04106384
Linked	E2B_04106384
Linked	E2B_04106384
Linked	E2B_04106384
Linked	E2B_04106384

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AMITRIPTYLINE	Concomitant		Unknown				Product used for unknown indication
ASA	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication
COVID-19 VACCINE	Suspect		Unknown				COVID-19 immunisation

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
FOLIC ACID	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication
HYDROXYCHLOROQUINE SULFATE	Concomitant		Unknown				Product used for unknown indication
LANSOPRAZOLE	Concomitant	CAPSULE, DELAYED RELEASE	Unknown				Product used for unknown indication
LEVOTHYROXINE SODIUM	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication
METFORMIN	Concomitant		Unknown				Product used for unknown indication
METHOTREXATE	Concomitant		Unknown				Product used for unknown indication
OLMESARTAN	Concomitant		Unknown				Product used for unknown indication
ORENCIA	Suspect		Intravenous (not otherwise specified)	750.0 Milligram	1 every 4 Weeks		Rheumatoid arthritis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	
Gingival erythema	v.24.1	
Inappropriate schedule of product administration	v.24.1	248 Days
Intentional product use issue	v.24.1	
Migraine	v.24.1	
Nasopharyngitis	v.24.1	
Rhinorrhoea	v.24.1	9 Days
Spinal disorder	v.24.1	
Urticaria	v.24.1	
Weight decreased	v.24.1	
Weight increased	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Wheezing	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04589367	0	2021-08-24	2021-08-24	MAH	202101022886	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
67 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Myocarditis	v.24.1	
Pancreatitis acute	v.24.1	
Pleural effusion	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04589505	1	2021-08-24	2021-12-06	MAH	202101028146	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
73 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Duplicate	E2B_04573401

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BRODALUMAB	Suspect		Subcutaneous	210.0 Milligram	1 every 1 Weeks	15.0 Days	Psoriasis
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
ERGOCALCIFEROL	Concomitant	NOT SPECIFIED	Unknown				
FOLIC ACID	Concomitant	NOT SPECIFIED	Unknown				
OMEGA 3 [FISH OIL]	Concomitant	Capsules	Unknown				
PROPRANOLOL HYDROCHLORIDE	Concomitant		Unknown				Tremor
XANTOFYL PALMITATE	Concomitant		Unknown				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Eye haemorrhage	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Myalgia	v.24.1	
Vaccination site erythema	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:08:27 AM
Initial Received Date:	2021-07-30 to 2021-09-30
Latest Received Date:	N/A
Total Number of Reports:	703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04589513	0	2021-08-24	2021-08-24	MAH	2021841205	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
62 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CAMRELIZUMAB	Concomitant						
ESCITALOPRAM	Concomitant	Tablets					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04589609	0	2021-08-24	2021-08-24	MAH	202101064917	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
13 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Deep vein thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04589724	0	2021-08-24	2021-08-24	MAH	21K-028-4001320-00	Study	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
69 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular			1.0 Days	COVID-19 prophylaxis
COVID-19 VACCINE	Suspect		Intramuscular			0.0	COVID-19 prophylaxis
HUMIRA	Suspect	Solution for injection in pre-filled pen	Subcutaneous	40.0 Milligram	1 every 2 Weeks		Rheumatoid arthritis
HUMIRA	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous	40.0 Milligram	1 every 2 Weeks	113.0 Days	Rheumatoid arthritis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Aphthous ulcer	v.24.1	
Blood sodium decreased	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	
Haemoglobin decreased	v.24.1	
Haemorrhage	v.24.1	
Hypophagia	v.24.1	
Malaise	v.24.1	
Oropharyngeal pain	v.24.1	
Pneumonia	v.24.1	
Somnolence	v.24.1	
Vaccination complication	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04591954	1	2021-08-25	2021-09-07	MAH	MOD-2021-290879	Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
24 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Unknown	1.0 Dosage forms			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Myocarditis	v.24.1	
Vaccination complication	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04593479	1	2021-08-25	2021-09-03	MAH	2021A684739	Study	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
65 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ADVAIR	Concomitant	NOT SPECIFIED	Unknown				
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Immunisation
DESOXIMETASONE	Concomitant	NOT SPECIFIED	Unknown				
INH	Concomitant	NOT SPECIFIED	Unknown				
ORENCIA	Suspect		Intravenous (not otherwise specified)	750.0 Milligram	1 every 1 Months		Rheumatoid arthritis
TYLENOL	Concomitant	NOT SPECIFIED	Unknown				
VENLAFAXINE HYDROCHLORIDE	Concomitant		Unknown				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Breast abscess	v.24.1	24 Days
Fatigue	v.24.1	
Hypersomnia	v.24.1	
Injection site pain	v.24.1	
Nodule	v.24.1	
Pain	v.24.1	
Skin disorder	v.24.1	24 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04594271	3	2021-08-25	2021-12-03	MAH	2018SA310104	Study	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
49 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETAMINOPHEN	Concomitant	NOT SPECIFIED	Intravenous drip			11.0 Days	Premedication
ACYCLOVIR	Concomitant		Oral	200.0 Milligram		11.0 Days	Premedication
ALEMTUZUMAB	Suspect		Intravenous drip	12.0 Milligram	1 every 1 Days	3.0 Days	Relapsing-remitting multiple sclerosis
ALEMTUZUMAB	Suspect	Concentrate for solution for infusion	Intravenous drip	12.0 Milligram	1 every 1 Days	2.0 Days	Relapsing-remitting multiple sclerosis
BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE]	Concomitant		Oral	50.0 Milligram		11.0 Days	Premedication
COVID-19 VACCINE	Suspect		Unknown				COVID-19 immunisation
FROVATRIPTAN	Concomitant		Oral	2.5 Milligram			

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
GABAPENTIN	Concomitant		Unknown				
GABAPENTIN	Concomitant	NOT SPECIFIED	Oral	300.0 Milligram			
GRAVOL	Concomitant	NOT SPECIFIED	Oral	50.0 Milligram		11.0 Days	Premedication
METHYLPREDNISOLONE	Concomitant		Intravenous (not otherwise specified)	1.0 Gram		11.0 Days	Premedication
MIRTAZAPINE	Concomitant	Tablets	Oral	45.0 Milligram			
NAPROXEN	Concomitant	NOT SPECIFIED	Oral	500.0 Milligram			
NORTRIPTYLINE	Concomitant	Capsules	Oral	25.0 Milligram			
RANITIDINE	Concomitant		Oral	150.0 Milligram		11.0 Days	Premedication
VENLAFAXINE	Concomitant		Oral	37.5 Milligram			
VITAMIN B 12 [VITAMIN B12 NOS]	Concomitant		Unknown				
VITAMIN D	Concomitant	NOT SPECIFIED	Unknown				
VITAMIN E NOS	Concomitant		Unknown				
ZOLMITRIPTAN	Concomitant	NOT SPECIFIED	Oral	5.0 Milligram			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain upper	v.24.1	3 Days
Alopecia	v.24.1	
Atypical pneumonia	v.24.1	
Blood pressure increased	v.24.1	6 Days
Chest pain	v.24.1	
Cough	v.24.1	
Decreased appetite	v.24.1	3 Days
Diarrhoea	v.24.1	6 Days
Gait disturbance	v.24.1	
Haemophagocytic lymphohistiocytosis	v.24.1	
Headache	v.24.1	8 Days
Heart rate increased	v.24.1	2 Days
Hyperhidrosis	v.24.1	3 Days
Illness	v.24.1	
Influenza	v.24.1	
Infusion site pain	v.24.1	9 Days

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Malaise	v.24.1	
Migraine	v.24.1	
Nasopharyngitis	v.24.1	
Nausea	v.24.1	6 Days
Nausea	v.24.1	3 Days
Oral herpes	v.24.1	4 Days
Oropharyngeal pain	v.24.1	
Pain in extremity	v.24.1	
Paraesthesia	v.24.1	1 Days
Renal disorder	v.24.1	
Sinusitis	v.24.1	
Vertigo	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04595016	0	2021-08-25	2021-08-25	MAH	202101046759	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female	49 Centimeter	3 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypoglycaemia neonatal	v.24.1	
Maternal exposure during pregnancy	v.24.1	
Weight decrease neonatal	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04595132	0	2021-08-25	2021-08-25	MAH	202101033656	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
33 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETAMINOPHEN	Concomitant	NOT SPECIFIED	Oral	975.0 Milligram			Premedication
ACYCLOVIR	Concomitant		Oral	200.0 Milligram	2 every 1 Days		
ALEMTUZUMAB	Suspect	SOLUTION INTRAVENOUS	Intravenous drip	12.0 Milligram	1 every 1 Days	5.0 Days	Relapsing-remitting multiple sclerosis
BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE]	Concomitant		Oral	25.0 Milligram			Premedication
CETIRIZINE HYDROCHLORIDE	Concomitant		Oral	10.0 Milligram	2 every 1 Days	5.0 Days	Premedication
COVID-19 VACCINE	Suspect		Unknown		Total		COVID-19 immunisation
GRAVOL	Concomitant	NOT SPECIFIED	Oral	50.0 Milligram			Premedication

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
METHYLPREDNISOLONE	Concomitant		Intravenous (not otherwise specified)	1.0 Gram		5.0 Days	Premedication
OXYBUTYNIN	Concomitant	NOT SPECIFIED	Oral	5.0 Milligram	2 every 1 Days		
PROZAC	Concomitant	NOT SPECIFIED	Oral	60.0 Milligram	1 every 1 Days		
RANITIDINE	Concomitant		Oral	150.0 Milligram	2 every 1 Days	5.0 Days	Premedication
SERTRALINE	Concomitant	Capsules	Unknown	100.0 Milligram			
TOVIAZ	Concomitant	TABLET (EXTENDED-RELEASE)	Unknown	5.0 Milligram			
TRAZODONE	Concomitant		Unknown	150.0 Milligram			
TRAZODONE	Concomitant		Oral	150.0 Milligram	1 every 1 Days		
VITAMIN B COMPLEX	Concomitant		Oral		1 every 1 Days		
VITAMIN D [COLECALCIFEROL]	Concomitant		Oral		1 every 1 Days		
VYVANSE	Concomitant	Capsules	Oral	40.0 Milligram			Fatigue

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal distension	v.24.1	
Abdominal pain	v.24.1	
Abdominal pain lower	v.24.1	
Acne	v.24.1	
Anxiety	v.24.1	
Asthenia	v.24.1	
Balance disorder	v.24.1	
Bronchitis	v.24.1	
Burning sensation	v.24.1	
Chills	v.24.1	
Dairy intolerance	v.24.1	
Decreased appetite	v.24.1	
Depression	v.24.1	
Device occlusion	v.24.1	
Diarrhoea	v.24.1	
Dry skin	v.24.1	
Dyspnoea	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dysuria	v.24.1	
Fatigue	v.24.1	
Frustration tolerance decreased	v.24.1	
Headache	v.24.1	
Hiccups	v.24.1	
Hypersomnia	v.24.1	
Hypertension	v.24.1	
Infusion site extravasation	v.24.1	
Malaise	v.24.1	
Migraine	v.24.1	
Multiple sclerosis relapse	v.24.1	
Muscle spasms	v.24.1	
Musculoskeletal stiffness	v.24.1	
Nasal congestion	v.24.1	
Nausea	v.24.1	
Neck mass	v.24.1	
Neurogenic bladder	v.24.1	
Oropharyngeal pain	v.24.1	
Pain	v.24.1	
Pain in extremity	v.24.1	
Palpitations	v.24.1	
Pruritus	v.24.1	
Pyrexia	v.24.1	
Self esteem decreased	v.24.1	
Swelling	v.24.1	
Thirst	v.24.1	
Urinary incontinence	v.24.1	
Urinary tract infection	v.24.1	
Urine abnormality	v.24.1	
Urticaria	v.24.1	
Viral infection	v.24.1	
Vomiting	v.24.1	
White blood cells urine positive	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04595151	1	2021-08-25	2021-09-22	MAH	202101033707	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
44 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Duplicate	E2B_03615525

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
APIXABAN	Concomitant			10.0 Milligram	1 every 1 Days		
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
IMMUNOGLOBULIN (HUMAN)	Suspect		Subcutaneous	10.0 Gram	1 every 1 Weeks		Primary immunodeficiency syndrome
IMMUNOGLOBULIN (HUMAN)	Suspect	Solution for infusion	Subcutaneous	18.0 Gram	2 every 1 Weeks		Primary immunodeficiency syndrome
IRON	Concomitant		Unknown				
RANITIDINE	Concomitant		Unknown				
RUPATADINE FUMARATE	Concomitant		Unknown				
SINGULAIR	Concomitant	NOT SPECIFIED	Unknown				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood pressure increased	v.24.1	
Chills	v.24.1	
Cough	v.24.1	
Dyspnoea	v.24.1	
Fatigue	v.24.1	
Heart rate increased	v.24.1	
Infusion site bruising	v.24.1	
Infusion site haemorrhage	v.24.1	
Infusion site pain	v.24.1	
Infusion site swelling	v.24.1	
Malaise	v.24.1	
Mastocytosis	v.24.1	
Nausea	v.24.1	
Nervous system disorder	v.24.1	
Oxygen saturation decreased	v.24.1	
Pulmonary embolism	v.24.1	
Sinusitis	v.24.1	
Tachycardia	v.24.1	
Thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04595165	1	2021-08-25	2021-12-22	MAH	202101033680	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
57 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_04824917
Duplicate	E2B_04824917

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETAMINOPHEN	Concomitant	NOT SPECIFIED	Oral	975.0 Milligram			Premedication
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
FABRAZYME	Suspect	POWDER FOR SOLUTION INTRAVENOUS	Intravenous drip	80.0 Milligram			Fabry's disease
METOPROLOL	Concomitant		Unknown				
VITAMIN D [COLECALCIFEROL]	Concomitant		Unknown				
VITAMIN D [COLECALCIFEROL]	Concomitant		Unknown				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Acute pulmonary oedema	v.24.1	
Arrhythmia	v.24.1	
Asthenia	v.24.1	
Atrial fibrillation	v.24.1	
COVID-19	v.24.1	
Cardiac disorder	v.24.1	
Chest discomfort	v.24.1	
Drug ineffective	v.24.1	
Extrasystoles	v.24.1	
Fatigue	v.24.1	
Heart rate increased	v.24.1	
Heart rate irregular	v.24.1	
Limb discomfort	v.24.1	
Myocardial necrosis marker increased	v.24.1	
Pain	v.24.1	
Pain in extremity	v.24.1	
Weight increased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04595171	0	2021-08-25	2021-08-25	MAH	202101034394	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
76 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Duplicate	E2B_04587510

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Heart rate irregular	v.24.1	
Malaise	v.24.1	
Migraine	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:08:27 AM
Initial Received Date:	2021-07-30 to 2021-09-30
Latest Received Date:	N/A
Total Number of Reports:	703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04595174	0	2021-08-25	2021-08-25	MAH	202101033876	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
83 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_04824939

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown		Total		COVID-19 immunisation
MEPOLIZUMAB	Suspect		Subcutaneous	100.0 Milligram			Asthma

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Constipation	v.24.1	
Pyrexia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04595269	1	2021-08-25	2021-08-31	MAH	202101033849	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
65 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ADVAIR	Concomitant	NOT SPECIFIED	Unknown				
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
DESOXIMETASONE	Concomitant	NOT SPECIFIED	Unknown				
INH	Concomitant	NOT SPECIFIED	Unknown				
ORENCIA	Suspect		Intravenous (not otherwise specified)	750.0 Milligram			Rheumatoid arthritis
TYLENOL	Concomitant	NOT SPECIFIED	Unknown				
VENLAFAXINE HYDROCHLORIDE	Concomitant		Unknown				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Breast abscess	v.24.1	24 Days
Fatigue	v.24.1	
Hypersomnia	v.24.1	
Nodule	v.24.1	
Pain	v.24.1	
Skin disorder	v.24.1	24 Days
Vaccination site pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04595289	0	2021-08-25	2021-08-25	MAH	202101034031	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
66 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
HUMIRA	Suspect	Solution for injection in pre-filled pen	Subcutaneous		Cyclical		Psoriatic arthropathy
HUMIRA	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous	40.0 Milligram	Cyclical	1460.0 Days	Psoriatic arthropathy

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pain	v.24.1	
Pneumonia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04595340	0	2021-08-25	2021-08-25	MAH	202101040127	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
53 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
EZETROL	Concomitant	Tablets					
LIPITOR	Concomitant	NOT SPECIFIED	Unknown				
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
TYLENOL	Concomitant	NOT SPECIFIED					
ZOMIG	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Sudden hearing loss	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04596009	0	2021-08-25	2021-08-25	MAH	202101034087	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
50 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total	1.0 Days	COVID-19 immunisation
HUMIRA	Suspect	Solution for injection	Subcutaneous	40.0 Milligram		730.0 Days	Psoriatic arthropathy
HUMIRA	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous	40.0 Milligram			Psoriatic arthropathy

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain	v.24.1	
Arthralgia	v.24.1	
Back pain	v.24.1	
Diarrhoea	v.24.1	
Drug ineffective	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Psoriasis	v.24.1	
Suspected COVID-19	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04596026	0	2021-08-25	2021-08-25	MAH	202101029446	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
51 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BUDESONIDE/FORMOTEROL FUMARATE	Concomitant						
LEVOTHYROXINE SODIUM	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
VENTOLIN [SALBUTAMOL]	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Burning sensation	v.24.1	
Chest pain	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Confusional state	v.24.1	
Dupuytren's contracture	v.24.1	
Erythema	v.24.1	
Face oedema	v.24.1	
Hyperhidrosis	v.24.1	
Lip swelling	v.24.1	
Pain	v.24.1	
Pain in extremity	v.24.1	
Palpitations	v.24.1	
Rash	v.24.1	
Skin exfoliation	v.24.1	
Swollen tongue	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04596052	0	2021-08-25	2021-08-25	MAH	202101047718	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
50 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PANTOPRAZOLE SODIUM	Concomitant		Oral				Burn of internal organs
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypoaesthesia	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Pruritus	v.24.1	
Rash	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04596061	0	2021-08-25	2021-08-25	MAH	202101047795	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
32 Years				Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MRNA-1273 SARS-COV-2	Suspect	NOT SPECIFIED	Intramuscular		Total	1.0 Days	COVID-19 immunisation
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	2 Days
Flushing	v.24.1	1 Days
Lichen planus	v.24.1	
Noninfective gingivitis	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Skin lesion	v.24.1	
Stomatitis	v.24.1	
Tongue disorder	v.24.1	
Tongue geographic	v.24.1	
Vitamin B12 decreased	v.24.1	
Vulvovaginal mycotic infection	v.24.1	
Vulvovaginal pruritus	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04596098	0	2021-08-25	2021-08-25	MAH	2021665525	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Dysgeusia	v.24.1	
Dyspnoea	v.24.1	
Malaise	v.24.1	
Swelling face	v.24.1	
Urticaria	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:08:27 AM
Initial Received Date:	2021-07-30 to 2021-09-30
Latest Received Date:	N/A
Total Number of Reports:	703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04596209	1	2021-08-25	2021-08-26	MAH	202101034135	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
FAMPYRA	Suspect	TABLET (EXTENDED-RELEASE)	Unknown				Multiple sclerosis
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Therapeutic product effect decreased	v.24.1	
Vaccination complication	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04596281	0	2021-08-25	2021-08-25	MAH	202101034594	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
44 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Heavy menstrual bleeding	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Menstruation delayed	v.24.1	
Menstruation irregular	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04596292	0	2021-08-25	2021-08-25	MAH	202101033904	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
82 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total	31.0 Days	COVID-19 immunisation
HUMIRA	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous	40.0 Milligram			Rheumatoid arthritis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.24.1	
Drug ineffective	v.24.1	
Muscle spasms	v.24.1	
Musculoskeletal stiffness	v.24.1	
Pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04596330	0	2021-08-25	2021-08-25	MAH	202101029856	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
63 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Back pain	v.24.1	
Fatigue	v.24.1	
Migraine	v.24.1	10 Days
Pain in extremity	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04596379	0	2021-08-25	2021-08-25	MAH	202101034635	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
57 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETYLSALICYLIC ACID	Concomitant		Oral				Varicose vein
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal discomfort	v.24.1	
Arthralgia	v.24.1	0
Food allergy	v.24.1	
Gastrointestinal disorder	v.24.1	
Malaise	v.24.1	1 Days

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pharyngeal swelling	v.24.1	
Pruritus	v.24.1	
Rash	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04596383	0	2021-08-25	2021-08-25	MAH	202101068769	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
74 Years	Male			Recovered/resolved with sequelae

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pericarditis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04596448	0	2021-08-25	2021-08-25	MAH	202101033978	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
74 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
HUMIRA	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous	40.0 Milligram	1 every 1 Weeks		Crohn's disease

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bacteraemia	v.24.1	
Dyspnoea	v.24.1	
Headache	v.24.1	
Pyrexia	v.24.1	
Tremor	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04596560	1	2021-08-25	2021-08-26	MAH	202101033990	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
59 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
HUMIRA	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous	40.0 Milligram			Crohn's disease
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Crohn's disease	v.24.1	
Gastrointestinal scarring	v.24.1	
Headache	v.24.1	
Hypertension	v.24.1	
Large intestinal stenosis	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Malaise	v.24.1	
Small intestinal stenosis	v.24.1	
Vaccination site pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04596564	0	2021-08-25	2021-08-25	MAH	202101041556	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
67 Years				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_04601403
Linked	E2B_04601403
Linked	E2B_04601403
Linked	E2B_04601403

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04597046	1	2021-08-26	2021-09-09	MAH	2021A695114	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
63 Years	Female	165 Centimeter	71 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.5 ml			Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Inappropriate schedule of product administration	v.24.1	
Thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04599131	1	2021-08-26	2021-09-14	MAH	202101046386	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
51 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_05306577
Linked	E2B_05306577

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
NUVARING	Concomitant	RING (SLOW-RELEASE)					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
VITAMIN D	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
C-reactive protein increased	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Pericarditis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04599368	0	2021-08-26	2021-08-26	MAH	202101055977	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
28 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
VITAMINS NOS	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Condition aggravated	v.24.1	
Cyanosis	v.24.1	
Hypertension	v.24.1	
Muscle twitching	v.24.1	
Neuralgia	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pericarditis	v.24.1	
Postural orthostatic tachycardia syndrome	v.24.1	
Stiff tongue	v.24.1	
Supraventricular tachycardia	v.24.1	
Tremor	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04599452	0	2021-08-26	2021-08-26	MAH	202101046958	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
50 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Back pain	v.24.1	
Dizziness	v.24.1	
Erythema	v.24.1	
Fall	v.24.1	
Headache	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypersensitivity	v.24.1	
Mobility decreased	v.24.1	
Myalgia	v.24.1	
Nausea	v.24.1	
Neck pain	v.24.1	
Pain in extremity	v.24.1	
Paraesthesia	v.24.1	
Pruritus	v.24.1	
Syncope	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04599874	0	2021-08-26	2021-08-26	MAH	202101048123	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bell's palsy	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04600179	1	2021-08-26	2021-09-02	MAH	202101074931	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
31 Years	Female			Recovered/resolved with sequelae

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Diabetic ketoacidosis	v.24.1	
Type 1 diabetes mellitus	v.24.1	0

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04600484	0	2021-08-26	2021-08-26	MAH	2021840698	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ESCITALOPRAM OXALATE	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.24.1	-128
Chills	v.24.1	
Drug ineffective	v.24.1	
Dyspnoea	v.24.1	
Fatigue	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Nasal congestion	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:08:27 AM
Initial Received Date:	2021-07-30 to 2021-09-30
Latest Received Date:	N/A
Total Number of Reports:	703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04600486	0	2021-08-26	2021-08-26	MAH	202101058010	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
48 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CLOBAZAM	Concomitant	Tablets					
COLCHICINE	Concomitant	Tablets					
NEURONTIN	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Back pain	v.24.1	
Bradycardia	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest discomfort	v.24.1	
Chest pain	v.24.1	
Dysgeusia	v.24.1	
Dyspnoea	v.24.1	
Fatigue	v.24.1	
Gait disturbance	v.24.1	
Gingival blister	v.24.1	
Headache	v.24.1	
Nausea	v.24.1	
Oral pain	v.24.1	
Ovulation pain	v.24.1	
Pain in extremity	v.24.1	
Palpitations	v.24.1	
Paraesthesia	v.24.1	
Photophobia	v.24.1	
Polymenorrhoea	v.24.1	
Thirst	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04600521	0	2021-08-26	2021-08-26	MAH	202101046627	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
40 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Heavy menstrual bleeding	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04600669	0	2021-08-26	2021-08-26	MAH	202101057818	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
30 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Months	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dysmenorrhoea	v.24.1	
Menstrual disorder	v.24.1	
Premenstrual syndrome	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04600945	4	2021-08-26	2021-09-30	MAH	CA202027986	Study	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
31 Years	Female		99 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETYLSALICYLIC ACID	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication
ACETYLSALICYLIC ACID	Concomitant		Oral	81.0 Milligram			
AGALSIDASE ALFA	Suspect	Concentrate for solution for infusion	Unknown	6.0 Dosage forms	1 every 2 Weeks		Fabry's disease
AGALSIDASE ALFA	Suspect		Unknown	19.36 Milligram	1 every 2 Weeks		Fabry's disease
AGALSIDASE ALFA	Suspect	Concentrate for solution for infusion	Unknown	5.0 Dosage forms	2 every 1 Weeks		Fabry's disease
AGALSIDASE ALFA	Suspect	Concentrate for solution for infusion	Unknown	6.0 Dosage forms	1 every 2 Weeks		Fabry's disease
AGALSIDASE ALFA	Suspect	Concentrate for solution for infusion	Unknown		1 every 2 Weeks		Fabry's disease

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AGALSIDASE ALFA	Suspect	Concentrate for solution for infusion	Unknown	5.0 Dosage forms	1 every 2 Weeks		Fabry's disease
CALCIUM CARBONATE/MAGNESIUM CARBONATE/MAGNESIUM TRISILICATE	Concomitant		Unknown				
CALCIUM D-PANTOTHENATE/ERGOCALCIFEROL/NICOTINAMIDE/PYRIDOXINE HYDROCHLORIDE/RETINOL PALMITATE/RIBOFLAVIN/THIAMINE MONONITRATE/VITAMIN B12/VITAMIN C	Concomitant		Unknown				
COVID-19 VACCINE	Suspect		Unknown				Immunisation
DICLECTIN	Concomitant	TABLET (DELAYED-RELEASE)	Unknown	10.0 Milligram			
DOXYLAMINE	Concomitant		Unknown				
ERGOCALCIFEROL	Concomitant		Unknown				Product used for unknown indication
IMODIUM	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication
LIOTHYRONINE SODIUM	Concomitant		Unknown				Product used for unknown indication
MAGNESIUM PIDOLATE	Concomitant		Unknown				
MIRENA	Concomitant	INSERT (EXTENDED-RELEASE)	Intra-uterine				Product used for unknown indication
TYLENOL	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication
ZANTAC	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood pressure decreased	v.24.1	
Body temperature increased	v.24.1	
COVID-19 immunisation	v.24.1	
Cholestasis of pregnancy	v.24.1	
Exposure during pregnancy	v.24.1	10 Months
Fatigue	v.24.1	
Heart rate increased	v.24.1	
Hypoacusis	v.24.1	
Illness	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Increased appetite	v.24.1	
Infusion related reaction	v.24.1	
Malaise	v.24.1	
Maternal exposure during breast feeding	v.24.1	
Morning sickness	v.24.1	
Muscle spasms	v.24.1	
Nausea	v.24.1	
Pre-eclampsia	v.24.1	
Product dose omission issue	v.24.1	
Protein urine present	v.24.1	
Pruritus	v.24.1	
Vomiting	v.24.1	16 Days
Weight decreased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04601362	0	2021-08-26	2021-08-26	MAH	202101056005	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
39 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ESCITALOPRAM	Concomitant	Tablets					
METHYLPHENIDATE HYDROCHLORIDE	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Myocarditis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04601477	0	2021-08-26	2021-08-26	MAH	202101048627	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
25 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Seizure	v.24.1	
Syncope	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:08:27 AM
Initial Received Date:	2021-07-30 to 2021-09-30
Latest Received Date:	N/A
Total Number of Reports:	703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04602058	0	2021-08-27	2021-08-27	MAH	MOD-2021-293925	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
51 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETYLSALICYLIC ACID	Concomitant		Unknown				Product used for unknown indication
ALTACE	Concomitant	Capsules	Unknown				Product used for unknown indication
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Unknown	1.0 Dosage forms			COVID-19 immunisation
LIPITOR	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication
METFORMIN	Concomitant		Unknown				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cerebrovascular accident	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04602063	0	2021-08-27	2021-08-27	MAH	MOD-2021-293862	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
19 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CLONAZEPAM	Concomitant	Tablets	Unknown				Musculoskeletal stiffness
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Unknown	1.0 Dosage forms			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Loss of consciousness	v.24.1	
Lung disorder	v.24.1	
Pneumonia	v.24.1	
Pneumothorax	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Product dose omission issue	v.24.1	
Somnolence	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04602793	0	2021-08-27	2021-08-27	MAH	CA2021AMR180408	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
44 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	
Linked	
Linked	
Linked	E2B_03227163
Linked	
Linked	
Linked	
Linked	
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MEPOLIZUMAB	Suspect		Subcutaneous	100.0 Milligram			Asthma

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect		Unknown				Product used for unknown indication, COVID-19 prophylaxis
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown				Product used for unknown indication, COVID-19 prophylaxis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pneumonia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04604081	0	2021-08-27	2021-08-27	MAH	202101063145	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
27 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Ageusia	v.24.1	
Constipation	v.24.1	
Gastrooesophageal reflux disease	v.24.1	
Impaired gastric emptying	v.24.1	
Pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04604162	0	2021-08-27	2021-08-27	MAH	2021715283	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
76 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04604179	0	2021-08-27	2021-08-27	MAH	2021797069	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
25 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Angina pectoris	v.24.1	
Chest discomfort	v.24.1	
Dyspnoea	v.24.1	
Hypoaesthesia	v.24.1	
Menstrual disorder	v.24.1	
Vaginal haemorrhage	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04604190	0	2021-08-27	2021-08-27	MAH	2021BI01042367	Study	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
44 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				COVID-19 prophylaxis
TYSABRI	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	300.0 Milligram	1 every 4 Weeks		Multiple sclerosis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Acarodermatitis	v.24.1	
Fatigue	v.24.1	
Irritability	v.24.1	
Perennial allergy	v.24.1	
Therapeutic response shortened	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Urticaria	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04604593	0	2021-08-27	2021-08-27	MAH	202101056043	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
40 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_04577460
Linked	E2B_04577460

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BETA-CAROTENE/CALCIUM SULFATE/D-ALPHA TOCOPHERYL ACETATE/FERROUS FUMARATE/FOLIC ACID/NICOTINAMIDE/PYRIDOXINE HYDROCHLORIDE/RIBOFLAVIN/THIAMINE MONONITRATE/VITAMIN A ACETATE/VITAMIN B12/VITAMIN C/VITAMIN D3/ZINC OXIDE	Concomitant						

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
RABEPRAZOLE	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Inappropriate schedule of product administration	v.24.1	
Maternal exposure during pregnancy	v.24.1	
Premature labour	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04605025	0	2021-08-27	2021-08-27	MAH	202101096260	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pulmonary embolism	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04605026	0	2021-08-27	2021-08-27	MAH	202101096651	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
39 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
LORATADINE	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypoaesthesia oral	v.24.1	
Laryngeal oedema	v.24.1	
Paraesthesia oral	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04605406	0	2021-08-27	2021-08-27	MAH	202101080815	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
13 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.24.1	
Disturbance in attention	v.24.1	
Fatigue	v.24.1	
Muscular weakness	v.24.1	
Myocarditis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04605581	1	2021-08-27	2021-12-09	MAH	CA202027565	Study	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
76 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AZATHIOPRINE	Concomitant	NOT SPECIFIED	Unknown	75.0 Milligram	1 every 1 Days		
CANDESARTAN	Concomitant		Unknown	4.0 Milligram	1 every 1 Days		Hypertension
COVID-19 VACCINE	Suspect		Unknown				Product used for unknown indication
GAMMAGARD LIQUID ALSO KNOW AS IMMUNE GLOBULIN (HUMAN)	Concomitant	SOLUTION INTRAVENOUS	Unknown			193.0 Days	
HYDRALAZINE	Concomitant		Unknown	50.0 Milligram	3 every 1 Days		Hypertension
HYDRALAZINE	Concomitant		Unknown	10.0 Milligram			Hypertension
IMMUNOGLOBULIN (HUMAN)	Suspect		Unknown	8.0 Gram	1 every 1 Weeks		Primary immunodeficiency syndrome

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PREDNISONE	Concomitant	NOT SPECIFIED	Unknown	15.0 Milligram	1 every 1 Days		
PREGABALIN	Concomitant		Unknown	50.0 Milligram	2 every 1 Days		Trigeminal neuralgia
PREGABALIN	Concomitant	Capsules	Unknown	75.0 Milligram	2 every 1 Days		Trigeminal neuralgia

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Adverse drug reaction	v.24.1	
COVID-19 immunisation	v.24.1	
Dermatomyositis	v.24.1	
Hypotension	v.24.1	
Trigeminal neuralgia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04606097	1	2021-08-27	2021-08-30	MAH	MOD-2021-293182	Spontaneous	Consumer/other non health professional

Serious report?	Death:	Yes	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Fatal

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Unknown	1.0 Dosage forms			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Death	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04606107	0	2021-08-27	2021-08-27	MAH	MOD-2021-293144	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Unknown	1.0 Dosage forms			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blindness	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04606324	0	2021-08-27	2021-08-27	MAH	202101063074	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
31 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Drug interaction	v.24.1	
Maternal exposure before pregnancy	v.24.1	
Pregnancy on oral contraceptive	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04606606	0	2021-08-27	2021-08-27	MAH	MOD-2021-293009	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
47 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	Injection	Intramuscular	1.0 Dosage forms			COVID-19 immunisation
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	1.0 Dosage forms			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Electric shock sensation	v.24.1	2 Days
Hemiparaesthesia	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Tinnitus	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04606616	0	2021-08-27	2021-08-27	MAH	MOD-2021-293108	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Unknown	1.0 Dosage forms			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Seizure	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:08:27 AM
Initial Received Date:	2021-07-30 to 2021-09-30
Latest Received Date:	N/A
Total Number of Reports:	703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04606627	0	2021-08-27	2021-08-27	MAH	2021690826	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
36 Years	Female	152 Centimeter	58 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_04489614

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CIMZIA	Concomitant	Solution for injection	Oral				Polyarthritis
FOLIC ACID	Concomitant	NOT SPECIFIED	Oral		every 1 Days		Pregnancy
HYDROXYCHLOROQUINE SULFATE	Concomitant		Oral		every 1 Days		Polyarthritis
IRON	Concomitant		Oral		every 1 Days		Pregnancy
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
VITAMIN C [ASCORBIC ACID]	Concomitant		Oral		every 1 Days		Pregnancy
VITAMIN D [COLECALCIFEROL]	Concomitant		Oral		1 every 1 Weeks		Pregnancy

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Inappropriate schedule of product administration	v.24.1	
Maternal exposure during pregnancy	v.24.1	
Puerperal pyrexia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04607096	1	2021-08-27	2021-09-07	MAH	MOD-2021-292865	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
57 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	Injection	Intramuscular	1.0 Dosage forms			COVID-19 immunisation
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	1.0 Dosage forms			COVID-19 immunisation
PROGESTERONE	Concomitant			100.0 Milligram			Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Generalised tonic-clonic seizure	v.24.1	
Seizure	v.24.1	
Stress	v.24.1	
Unresponsive to stimuli	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04607210	0	2021-08-27	2021-08-27	MAH	MOD-2021-292860	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Unknown	1.0 Dosage forms			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04607529	0	2021-08-27	2021-08-27	MAH	202101048855	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
26 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Inappropriate schedule of product administration	v.24.1	
Pericarditis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04607552	0	2021-08-27	2021-08-27	MAH	202101075960	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Transplacental		Total	1.0 Days	Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Exposure during pregnancy	v.24.1	
Hyperbilirubinaemia neonatal	v.24.1	
Positive airway pressure therapy	v.24.1	
Premature baby	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:08:27 AM
Initial Received Date:	2021-07-30 to 2021-09-30
Latest Received Date:	N/A
Total Number of Reports:	703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04607985	0	2021-08-27	2021-08-27	MAH	202101057849	Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
52 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blindness	v.24.1	
Deafness	v.24.1	
Inappropriate schedule of product administration	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04608891	1	2021-08-29	2021-09-09	MAH	202101064119	Spontaneous	Consumer/other non health professional

Serious report?
Serious

Death:	No	**Disability:**	No	**Congenital Anomaly:**	No
Life Threatening:	No	**Hospitalization:**	No	**Other Medically Important Conditions:**	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
65 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_04648938
Linked	E2B_04648938
Linked	E2B_04648938

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
VENLAFAXINE HYDROCHLORIDE	Concomitant		Oral				Anxiety

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Burning sensation	v.24.1	
Periarthritis	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Polymyalgia rheumatica	v.24.1	4 Months

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04610058	0	2021-08-30	2021-08-30	MAH	21K-028-4056200-00	Study	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
40 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular			1.0 Months	COVID-19 prophylaxis, COVID-19 immunisation
HUMIRA	Suspect	Solution for injection in pre-filled pen	Subcutaneous	40.0 Milligram	1 every 2 Weeks	181.0	Rheumatoid arthritis
HUMIRA	Suspect	Solution for injection in pre-filled pen	Subcutaneous	40.0 Milligram	1 every 2 Weeks		Rheumatoid arthritis
HUMIRA	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous	40.0 Milligram	1 every 2 Weeks	-134.0	Rheumatoid arthritis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Drug ineffective	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Injection site erythema	v.24.1	
Injection site pain	v.24.1	
Nail bed infection	v.24.1	
Oedema peripheral	v.24.1	2 Months
Rheumatoid arthritis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04610580	0	2021-08-30	2021-08-30	MAH	21K-028-3995443-00	Study	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
29 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular			0.0	COVID-19 prophylaxis
COVID-19 VACCINE	Suspect		Intramuscular			0.0	COVID-19 prophylaxis
HUMIRA	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous	40.0 Milligram	1 every 2 Weeks	-43.0	Rheumatoid arthritis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Drug ineffective	v.24.1	
Rheumatoid arthritis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:08:27 AM
Initial Received Date:	2021-07-30 to 2021-09-30
Latest Received Date:	N/A
Total Number of Reports:	703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04611095	1	2021-08-30	2021-10-04	MAH	2130153US	Spontaneous	Other health professional

Serious report?
Not Serious

Death:	No	**Disability:**	No	**Congenital Anomaly:**	No
Life Threatening:	No	**Hospitalization:**	No	**Other Medically Important Conditions:**	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
49 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BOTOX 50U/50ALLERGAN U VIAL, 100U/100ALLERGAN U VIAL, 200U/200ALLERGAN U VIAL	Suspect	Powder for injection	Unknown		1 every 1 Days	1.0 Days	Skin wrinkling
BOTOX 50U/50ALLERGAN U VIAL, 100U/100ALLERGAN U VIAL, 200U/200ALLERGAN U VIAL	Suspect	Powder for injection	Unknown		1 every 1 Days	1.0 Days	Skin wrinkling
BOTOX 50U/50ALLERGAN U VIAL, 100U/100ALLERGAN U VIAL, 200U/200ALLERGAN U VIAL	Suspect	Powder for injection	Unknown		1 every 1 Days	1.0 Days	Skin wrinkling

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BOTOX 50U/50ALLERGAN U VIAL, 100U/100ALLERGAN U VIAL, 200U/200ALLERGAN U VIAL	Suspect	POWDER FOR SOLUTION INTRAMUSCULAR	Unknown		1 every 1 Days	1.0 Days	Skin wrinkling
COVID-19 VACCINE	Suspect		Unknown	1.0 Dosage forms	1 every 1 Days	1.0 Months	COVID-19 immunisation
COVID-19 VACCINE	Suspect		Unknown	1.0 Dosage forms	1 every 1 Days	0.0	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Drug ineffective	v.24.1	
Drug ineffective	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04611858	0	2021-08-30	2021-08-30	MAH	202100942005	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
29 Years	Female	172 Centimeter	77 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
DOXYLAMINE	Concomitant		Oral		As required		Prophylaxis of nausea and vomiting
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
PROGESTERONE	Concomitant		Oral	200.0 Milligram	every 1 Days		Haematoma
VITAMINS NOS	Concomitant	Tablet	Oral		every 1 Days		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Haematoma	v.24.1	
Maternal exposure before pregnancy	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Vaginal haemorrhage	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04611861	0	2021-08-30	2021-08-30	MAH	2021868973	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
80 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CANDESARTAN	Concomitant		Oral				Hypertension
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Diarrhoea	v.24.1	
Dyspepsia	v.24.1	
Gait disturbance	v.24.1	
Headache	v.24.1	
Impaired quality of life	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Inappropriate schedule of product administration	v.24.1	
Nausea	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04613394	0	2021-08-30	2021-08-30	MAH	202101075025	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
57 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
HYDROXYCHLOROQUINE	Concomitant						
METHOTREXATE	Concomitant	NOT SPECIFIED		1.0 Dosage forms			
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Months	COVID-19 immunisation
XELJANZ	Suspect	Tablet	Oral	5.0 Milligram	2 every 1 Days		Rheumatoid arthritis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	
Feeling hot	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Poor quality sleep	v.24.1	
White blood cell count decreased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04614034	0	2021-08-30	2021-08-30	MAH	202101075959	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
33 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
ZANTAC	Concomitant	NOT SPECIFIED	Oral				Gastrooesophageal reflux disease

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.24.1	1 Hours
Inappropriate schedule of product administration	v.24.1	
Maternal exposure during pregnancy	v.24.1	
Pain in extremity	v.24.1	24 Hours

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04614918	0	2021-08-30	2021-08-30	MAH	202101109550	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
59 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anxiety	v.24.1	
Arthralgia	v.24.1	
Chest pain	v.24.1	
Palpitations	v.24.1	
Supraventricular tachycardia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04615020	0	2021-08-30	2021-08-30	MAH	202101064144	Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bell's palsy	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04616050	0	2021-08-31	2021-08-31	MAH	2021A704354	Spontaneous	Physician

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Product used for unknown indication
METFORMIN	Concomitant						
METHOTREXATE	Concomitant	NOT SPECIFIED	Intrathecal				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Herpes zoster	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04617043	0	2021-08-31	2021-08-31	MAH	202100992822	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
55 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETYLSALICYLIC ACID	Concomitant		Oral				Thrombosis
LIPITOR	Concomitant	NOT SPECIFIED	Oral				Blood cholesterol
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Acne	v.24.1	
Dry skin	v.24.1	
Emotional disorder	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Eyelid skin dryness	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Mobility decreased	v.24.1	
Pain in extremity	v.24.1	
Pruritus	v.24.1	
Psoriasis	v.24.1	
Rash morbilliform	v.24.1	
Varicella	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04617101	0	2021-08-31	2021-08-31	MAH	202101064270	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
64 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AMLODIPINE	Concomitant	Tablets		5.0 Milligram			
IRBESARTAN	Concomitant	Tablets		150.0 Milligram	every 1 Days		
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bell's palsy	v.24.1	
Herpes zoster	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Vertigo	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:08:27 AM
Initial Received Date:	2021-07-30 to 2021-09-30
Latest Received Date:	N/A
Total Number of Reports:	703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04617115	1	2021-08-31	2021-12-20	MAH	202101075365	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
52 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown		Total		COVID-19 immunisation
INFLIXIMAB	Concomitant		Intravenous (not otherwise specified)	300.0 Milligram			Psoriatic arthropathy
SALAZOPYRIN	Concomitant	NOT SPECIFIED		1500.0 Milligram	every 1 Days		Psoriatic arthropathy

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.24.1	-151
Cough	v.24.1	-151
Drug ineffective	v.24.1	-151

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04617289	0	2021-08-31	2021-08-31	MAH	202101065051	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cardiac disorder	v.24.1	
Gastrointestinal disorder	v.24.1	
Lung disorder	v.24.1	
Nervous system disorder	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04617906	0	2021-08-31	2021-08-31	MAH	202101064222	Published	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
84 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Atrial fibrillation	v.24.1	
Disease recurrence	v.24.1	
Immune thrombocytopenia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04618246	0	2021-08-31	2021-08-31	MAH	202101064993	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
52 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Diabetes mellitus	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04618357	0	2021-08-31	2021-08-31	MAH	202101069851	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
31 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dysmenorrhoea	v.24.1	
Heavy menstrual bleeding	v.24.1	
Menstrual disorder	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04618376	1	2021-08-31	2021-09-15	MAH	202101068648	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
39 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	E2B_04672873
Linked	E2B_04672873

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CITRULLINE	Concomitant		Oral				Hormone level abnormal, Depression
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04618488	0	2021-08-31	2021-08-31	MAH	202101068462	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
32 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Seizure	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04618563	0	2021-08-31	2021-08-31	MAH	202101090813	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
61 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Erythema	v.24.1	
Pain	v.24.1	
Swelling	v.24.1	
Thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04618874	0	2021-08-31	2021-08-31	MAH	202101068461	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
26 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Heavy menstrual bleeding	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Intermenstrual bleeding	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04618971	0	2021-08-31	2021-08-31	MAH	2021A704179	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
26 Years	Female	165 Centimeter	63 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.5 ml			Product used for unknown indication
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	0.5 ml			Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Menstruation delayed	v.24.1	
Pregnancy test negative	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:08:27 AM
Initial Received Date:	2021-07-30 to 2021-09-30
Latest Received Date:	N/A
Total Number of Reports:	703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04619019	4	2021-08-31	2021-12-14	MAH	2018MPI014438	Study	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
70 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACYCLOVIR /00587301/	Concomitant		Oral	200.0 Milligram	2 every 1 Days		
AMLODIPINE	Concomitant	Tablets	Oral	10.0 Milligram	1 every 1 Days		
ASPIRIN /00002701/	Concomitant		Oral	81.0 Milligram	1 every 1 Days		
ATENOLOL	Concomitant	Tablets	Oral	25.0 Milligram	1 every 1 Days		
BACLOFEN	Concomitant	NOT SPECIFIED	Oral	5.0 Milligram	2 every 1 Days		
CALCIUM/MAGNESIUM/VITAMIN D3	Concomitant	Tablet	Oral		1 every 1 Days		
COVID-19 VACCINE	Suspect		Intramuscular	30.0 Microgram			Product used for unknown indication
COVID-19 VACCINE	Suspect		Intramuscular	30.0 Microgram			Product used for unknown indication
CYCLOPHOSPHAMIDE	Concomitant		Unknown				
CYCLOPHOSPHAMIDE	Concomitant		Oral	50.0 Milligram	1 every 2 Days		
CYCLOPHOSPHAMIDE	Concomitant	NOT SPECIFIED	Unknown				
DEXAMETHASONE	Suspect	NOT SPECIFIED	Unknown				Product used for unknown indication
EPOETIN ALFA	Concomitant		Unknown		1 every 1 Weeks		
FERROUS FUMARATE	Concomitant	NOT SPECIFIED	Oral	300.0 Milligram	1 every 1 Days		
GLICLAZIDE	Suspect	Tablets	Unknown	30.0 Milligram	1 every 1 Days	76.0 Days	Blood glucose increased
GLICLAZIDE	Suspect		Unknown	15.0 Milligram	1 every 1 Days		Blood glucose increased
IXAZOMIB	Suspect	Capsules	Oral	3.0 Milligram			Plasma cell myeloma
IXAZOMIB	Suspect		Oral	3.0 Milligram		34.0 Days	Plasma cell myeloma
IXAZOMIB	Suspect	Capsules	Unknown				Plasma cell myeloma
IXAZOMIB	Suspect	Capsules	Unknown	2.3 Milligram			Plasma cell myeloma
IXAZOMIB	Suspect	Capsules	Unknown	2.3 Milligram			Plasma cell myeloma
NITROGLYCERIN	Concomitant		Transdermal	0.4 Milligram	1 every 1 Hours		

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ONDANSETRON	Suspect	NOT SPECIFIED	Unknown	8.0 Milligram			Premedication
PANTOPRAZOLE SODIUM	Concomitant		Oral	40.0 Milligram	1 every 1 Days		
PIOGLITAZONE HYDROCHLORIDE	Suspect		Oral	15.0 Milligram	1 every 1 Days		Diabetes mellitus
PREDNISONE	Concomitant		Oral	25.0 Milligram	1 every 2 Days		
PREDNISONE	Concomitant	NOT SPECIFIED	Oral	50.0 Milligram	1 every 2 Days		
QUININE	Concomitant		Unknown	200.0 Milligram	1 every 2 Days		Muscle spasms
REVLIMID	Concomitant	Capsules	Unknown	5.0 Milligram		54.0 Days	
REVLIMID	Concomitant		Unknown				
REVLIMID	Concomitant		Unknown	5.0 Milligram		14.0 Days	
ROSUVASTATIN	Concomitant	NOT SPECIFIED	Oral	5.0 Milligram	1 every 1 Days		
TERAZOSIN HYDROCHLORIDE	Concomitant		Oral	2.0 Milligram	1 every 1 Days		
TRAJENTA	Concomitant	Tablets	Oral	5.0 Milligram	1 every 1 Days		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19 immunisation	v.24.1	
Cardiac failure	v.24.1	
Clostridium difficile colitis	v.24.1	
Constipation	v.24.1	
Haemorrhoids	v.24.1	
Neuropathy peripheral	v.24.1	
Product use issue	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04619301	0	2021-08-31	2021-08-31	MAH	202101069311	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
37 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_04350894
Linked	E2B_04350894

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ETHINYL ESTRADIOL/LEVONORGESTREL	Concomitant				1 every 1 Days		
NORTRIPTYLINE	Concomitant	Capsules		50.0 Milligram			
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Inappropriate schedule of product administration	v.24.1	
Palpitations	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:08:27 AM
Initial Received Date:	2021-07-30 to 2021-09-30
Latest Received Date:	N/A
Total Number of Reports:	703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04619364	0	2021-08-31	2021-08-31	MAH	2021735797	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
33 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ESCITALOPRAM	Concomitant	Tablets					
NAPROXEN	Concomitant	NOT SPECIFIED					
OMEPRAZOLE	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown			1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.24.1	
Fatigue	v.24.1	
Inappropriate schedule of product administration	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Myalgia	v.24.1	
Pyrexia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04623444	0	2021-09-01	2021-09-01	MAH	202101068626	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
22 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Months	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Amenorrhoea	v.24.1	
Feeling abnormal	v.24.1	
Malaise	v.24.1	
Menstruation delayed	v.24.1	
Pain	v.24.1	
Pelvic pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04623508	0	2021-09-01	2021-09-01	MAH	202101068625	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
51 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Confusional state	v.24.1	
Dyspnoea	v.24.1	
Epistaxis	v.24.1	
Erection increased	v.24.1	
Feeling abnormal	v.24.1	
Flushing	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hyperhidrosis	v.24.1	
Insomnia	v.24.1	
Lung disorder	v.24.1	
Peripheral coldness	v.24.1	
Rectal haemorrhage	v.24.1	
Scrotal disorder	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04623904	0	2021-09-01	2021-09-01	MAH	202100934481	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown			1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Inappropriate schedule of product administration	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04623914	1	2021-09-01	2021-09-16	MAH	2021887474	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
49 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CANNABIS SATIVA	Concomitant						Back pain
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Diplopia	v.24.1	
Eye pain	v.24.1	
Gait disturbance	v.24.1	
Headache	v.24.1	
Interchange of vaccine products	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Loss of personal independence in daily activities	v.24.1	
Off label use	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04624000	0	2021-09-01	2021-09-01	MAH	202101081888	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown			1.0 Months	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Herpes zoster	v.24.1	
Peripheral swelling	v.24.1	
Urticaria	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04624072	0	2021-09-01	2021-09-01	MAH	2021840013	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
32 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
TYLENOL	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.24.1	10 Days
Headache	v.24.1	10 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04624612	0	2021-09-01	2021-09-01	MAH	2021585605	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
41 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Axillary mass	v.24.1	112 Hours
Inappropriate schedule of product administration	v.24.1	
Pain	v.24.1	4 Days
Pain	v.24.1	112 Hours

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04624633	0	2021-09-01	2021-09-01	MAH	202101081989	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Recovered/resolved with sequelae

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Angina pectoris	v.24.1	
Inappropriate schedule of product administration	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04624729	0	2021-09-01	2021-09-01	MAH	202101109628	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
19 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.24.1	
Vaccination failure	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04628319	0	2021-09-02	2021-09-02	MAH	202101081765	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
50 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETAMINOPHEN/OXYCODONE HYDROCHLORIDE	Concomitant		Oral				Pain
BUPROPION TEVA	Concomitant		Oral				Depression, Anxiety
DOXEPIN HYDROCHLORIDE	Concomitant		Oral				Depression, Anxiety
LEFLUNOMIDE	Concomitant	NOT SPECIFIED	Oral				Arthritis
METFORMIN HYDROCHLORIDE	Concomitant		Oral				
MIRTAZAPINE	Concomitant	Tablets	Oral				Depression, Anxiety

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
PRAZOSIN	Concomitant	Tablets	Oral				Depression, Anxiety
TRAZODONE HYDROCHLORIDE	Concomitant		Oral				Sleep disorder
ZOPICLONE	Concomitant		Oral				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Back pain	v.24.1	
Cough	v.24.1	
Dyspnoea	v.24.1	
Inappropriate schedule of product administration	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04628595	0	2021-09-02	2021-09-02	MAH	202101081995	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
21 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown			1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Angina pectoris	v.24.1	
Chest discomfort	v.24.1	
Dyspnoea	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04628633	0	2021-09-02	2021-09-02	MAH	202101081576	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
37 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hepatitis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04628711	0	2021-09-02	2021-09-02	MAH	202101082699	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
34 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BENADRYL	Concomitant	NOT SPECIFIED					Hypersensitivity
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bell's palsy	v.24.1	
Dehydration	v.24.1	
Muscular weakness	v.24.1	
Paraesthesia	v.24.1	
Tongue dry	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Vaccination site pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04628848	0	2021-09-02	2021-09-02	MAH	2021821197	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
22 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PAROXETINE HYDROCHLORIDE	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Tachycardia	v.24.1	2 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04628912	0	2021-09-02	2021-09-02	MAH	202101089870	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Myocarditis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04628960	1	2021-09-02	2021-09-08	MAH	202101096525	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
57 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CYCLOBENZAPRINE HYDROCHLORIDE	Concomitant		Oral				Intervertebral disc protrusion
FAMOTIDINE	Concomitant	NOT SPECIFIED	Oral				Abdominal discomfort
LIPITOR	Concomitant	NOT SPECIFIED	Oral				Blood cholesterol
LIXIANA	Concomitant	Tablets	Oral				Anticoagulant therapy
OXAZEPAM	Concomitant	Tablets					Sleep disorder
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
RAMIPRIL	Concomitant	NOT SPECIFIED	Oral				Blood pressure abnormal
SOTALOL	Concomitant		Oral				Atrial fibrillation
TRIMEBUTINE	Concomitant						Gastrointestinal disorder

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Atrial fibrillation	v.24.1	
Burning sensation	v.24.1	
Chest discomfort	v.24.1	
Fatigue	v.24.1	
Feeling hot	v.24.1	
Hypoaesthesia	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Musculoskeletal discomfort	v.24.1	
Palpitations	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04629383	0	2021-09-02	2021-09-02	MAH	202101084226	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
52 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_04629903
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood urine present	v.24.1	
Decreased appetite	v.24.1	
Fatigue	v.24.1	
Haemoglobin urine	v.24.1	
Kidney infection	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Leukocyturia	v.24.1	
Proteinuria	v.24.1	
Renal pain	v.24.1	
Urine analysis abnormal	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04629806	0	2021-09-02	2021-09-02	MAH	202101132622	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
37 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_04509824
Linked	E2B_04509824

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abortion missed	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:08:27 AM
Initial Received Date:	2021-07-30 to 2021-09-30
Latest Received Date:	N/A
Total Number of Reports:	703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04629903	0	2021-09-02	2021-09-02	MAH	202101098049	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
52 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_04629383

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood albumin increased	v.24.1	
Blood urine present	v.24.1	2 Months
Decreased appetite	v.24.1	
Fatigue	v.24.1	
Haemoglobin urine present	v.24.1	
Inappropriate schedule of product administration	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Kidney infection	v.24.1	
Pain	v.24.1	
Protein urine present	v.24.1	
Red blood cells urine positive	v.24.1	
Renal pain	v.24.1	
Urine abnormality	v.24.1	
White blood cells urine positive	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04632296	0	2021-09-03	2021-09-03	MAH	EMD Serono,a divisio	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
41 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CALCIUM [CALCIUM GLUCONATE]	Concomitant						Product used for unknown indication
COVID-19 VACCINE	Suspect						COVID-19 immunisation
COVID-19 VACCINE	Suspect						COVID-19 immunisation
MAGNESIUM [MAGNESIUM HYDROXIDE]	Concomitant						Product used for unknown indication
MAVENCLAD	Suspect	Tablet	Oral			10.0 Days	Multiple sclerosis
MAVENCLAD	Suspect	Tablets	Oral			10.0 Days	Multiple sclerosis

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
VITAMIN K1	Concomitant						Product used for unknown indication
ZINC	Concomitant	NOT SPECIFIED					Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood disorder	v.24.1	
Eye haemorrhage	v.24.1	
Eye pain	v.24.1	
Fatigue	v.24.1	
Fungal infection	v.24.1	
Lymphocyte count decreased	v.24.1	
Procedural pain	v.24.1	
Vitreous floaters	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04632965	0	2021-09-03	2021-09-03	MAH	MOD-2021-299502	Spontaneous	Consumer/other non health professional

Serious report?	Death:	Disability:	Congenital Anomaly:
Serious	Yes	No	No
	Life Threatening: No	**Hospitalization:** No	**Other Medically Important Conditions:** Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
40 Years	Male			Fatal

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Unknown	1.0 Dosage forms			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Death	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04633731	1	2021-09-03	2021-12-02	MAH	2018SA156218	Study	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
57 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ADVAIR	Concomitant	NOT SPECIFIED	Inhalation		1 every 1 Days		Asthma
APO-DOXEPIN	Concomitant	Capsules	Oral		1 every 1 Days		
BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE]	Concomitant		Oral		1 every 1 Days		Dermatitis atopic
CANDESARTAN	Concomitant		Oral	32.0 Milligram	1 every 1 Days		Hypertension
CICLOSPORIN	Concomitant		Unknown				
CICLOSPORIN	Concomitant	NOT SPECIFIED	Unknown				
COVID-19 VACCINE	Suspect		Unknown				Immunisation
DUPIXENT	Suspect	Suspension for injection in pre-filled syringe	Subcutaneous	300.0 Milligram	1 every 2 Weeks		Dermatitis atopic

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
DUPIXENT	Suspect	Suspension for injection in pre-filled syringe	Unknown				Dermatitis atopic
DUPIXENT	Suspect	Solution	Subcutaneous	600.0 Milligram	Total	1.0 Days	Dermatitis atopic
LYDERM [FLUOCINONIDE]	Concomitant	Ointment	Unknown				
METHOTREXATE	Concomitant	NOT SPECIFIED	Unknown				
PREDNISONE	Concomitant	NOT SPECIFIED	Unknown				
ROSUVASTATIN CALCIUM	Concomitant		Unknown				Blood cholesterol
SALBUTAMOL SULFATE	Concomitant		Inhalation		1 every 1 Days		Asthma

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Brain stem stroke	v.24.1	
Cerebellar stroke	v.24.1	
Dizziness	v.24.1	
Hospitalisation	v.24.1	
Scar	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04633844	0	2021-09-03	2021-09-03	MAH	2021SA289293	Study	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
53 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ATIVAN	Concomitant	NOT SPECIFIED	Unknown				
AUBAGIO	Suspect	Tablets	Oral	14.0 Milligram	1 every 1 Days		Relapsing-remitting multiple sclerosis
BACLOFEN	Concomitant	NOT SPECIFIED	Unknown				
BREXPIPRAZOLE	Concomitant		Unknown	0.5 Milligram			
CALCIUM	Concomitant	NOT SPECIFIED	Unknown				
COD LIVER OIL [COD-LIVER OIL]	Concomitant		Unknown				
COVID-19 VACCINE	Suspect		Unknown				COVID-19 immunisation
CYMBALTA	Concomitant	NOT SPECIFIED	Unknown				
DEXEDRINE	Concomitant	NOT SPECIFIED	Unknown				
IRBESARTAN	Concomitant	Tablets	Unknown				

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MAGNESIUM	Concomitant	NOT SPECIFIED	Unknown				
VITAMIN D3	Concomitant		Unknown	5000.0 IU (International Unit)			
ZOPICLONE	Concomitant	Tablets	Unknown				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal discomfort	v.24.1	
Diarrhoea	v.24.1	
Feeling abnormal	v.24.1	
Liver disorder	v.24.1	
Malaise	v.24.1	
Multiple sclerosis	v.24.1	
Nausea	v.24.1	
Oesophageal discomfort	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04633925	0	2021-09-03	2021-09-03	MAH	2021764713	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
49 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Postmenopausal haemorrhage	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04633943	0	2021-09-03	2021-09-03	MAH	2021613110	Spontaneous	Physician

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
62 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVERSYL [PERINDOPRIL ERBUMINE]	Concomitant		Oral	4.0 Milligram			Hypertension
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Erythema	v.24.1	
Headache	v.24.1	
Pruritus	v.24.1	
Skin burning sensation	v.24.1	
Swelling	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Urticaria chronic	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04633950	0	2021-09-03	2021-09-03	MAH	2021781686	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
41 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Menstrual disorder	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04634923	1	2021-09-03	2021-09-08	MAH	20210607838	Study	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
35 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown			1.0 Days	COVID-19 prophylaxis
STELARA	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous	90.0 Milligram	1 every 7 Days		Crohn's disease

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.24.1	1 Months

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cholangitis sclerosing	v.24.1	
Contrast media reaction	v.24.1	1 Days
Crohn's disease	v.24.1	
Hepatic enzyme increased	v.24.1	
Pyrexia	v.24.1	1 Months
Therapeutic response shortened	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04636450	0	2021-09-06	2021-09-06	MAH	MOD-2021-300134	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
40 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Unknown	1.0 Dosage forms			COVID-19 immunisation
GLUTATHIONE	Concomitant	NOT SPECIFIED	Unknown	1.0 Dosage forms			Supplementation therapy
TYLENOL	Concomitant	NOT SPECIFIED	Unknown	1.0 Dosage forms			Adverse drug reaction

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Gastrointestinal haemorrhage	v.24.1	
Pyrexia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04636572	0	2021-09-06	2021-09-06	MAH	MOD-2021-300140	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Unknown	1.0 Dosage forms			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Unevaluable event	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04636733	0	2021-09-06	2021-09-06	MAH	MOD-2021-297380	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
52 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	1.0 Dosage forms			COVID-19 immunisation
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	Injection	Intramuscular	1.0 Dosage forms			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bone pain	v.24.1	
Breast pain	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.24.1	
Inappropriate schedule of product administration	v.24.1	1 Days
Infection	v.24.1	
Mastitis	v.24.1	
Myalgia	v.24.1	
Oropharyngeal pain	v.24.1	
Pain	v.24.1	
Palpitations	v.24.1	
Product contamination	v.24.1	
Scar	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04637955	0	2021-09-06	2021-09-06	MAH	202101102061	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Condition aggravated	v.24.1	
Loss of personal independence in daily activities	v.24.1	
Reading disorder	v.24.1	
Vision blurred	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04637958	0	2021-09-06	2021-09-06	MAH	202101096727	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
35 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MINERALS NOS/VITAMINS NOS	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04638094	0	2021-09-06	2021-09-06	MAH	202101109515	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
61 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	
Neuropathy peripheral	v.24.1	
Pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04638095	0	2021-09-06	2021-09-06	MAH	202101132548	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
62 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hyperthyroidism	v.24.1	
Weight decreased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04639605	0	2021-09-06	2021-09-06	MAH	2021830077	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
47 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
TYLENOL	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cough	v.24.1	
Diarrhoea	v.24.1	
Fatigue	v.24.1	
Pain in extremity	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04639643	0	2021-09-06	2021-09-06	MAH	202101090319	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
62 Years	Female			Recovered/resolved with sequelae

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Inappropriate schedule of product administration	v.24.1	
Vertigo	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04640366	0	2021-09-07	2021-09-07	MAH	2021A714561	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
59 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.5 ml			COVID-19 immunisation
DEXILANT	Concomitant	CAPSULE, DELAYED RELEASE	Unknown				
PARIET	Concomitant	TABLET (ENTERIC-COATED)	Unknown	20.0 Milligram			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Sleep disorder	v.24.1	
Tinnitus	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04641787	3	2021-09-07	2021-12-20	MAH	20210228461	Study	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
58 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_03639178
Linked	
Linked	
Linked	E2B_03639178
Linked	
Linked	
Linked	E2B_03639178
Linked	
Linked	
Linked	E2B_03639178
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				COVID-19 prophylaxis

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
REMICADE	Suspect	POWDER FOR SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	800.0 Milligram	1 every 6 Weeks		Rheumatoid arthritis, Pyoderma gangrenosum, Psoriasis
SULFAMETHOXAZOLE/TRIMETHOPRIM	Concomitant	Tablet	Unknown	500.0 Milligram	2 every 1 Days		Prophylaxis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cellulitis	v.24.1	
Headache	v.24.1	1 Months
Infection	v.24.1	
Pain	v.24.1	1 Months
Pain in extremity	v.24.1	1 Months
Pyoderma gangrenosum	v.24.1	
Urinary tract infection	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04642004	0	2021-09-07	2021-09-07	MAH	2021A714729	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:08:27 AM
Initial Received Date:	2021-07-30 to 2021-09-30
Latest Received Date:	N/A
Total Number of Reports:	703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04642973	1	2021-09-07	2021-11-01	MAH	20210857577	Study	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
55 Years	Female		64 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				COVID-19 prophylaxis
STELARA	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous	90.0 Milligram	1 every 8 Weeks		Crohn's disease

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Diarrhoea	v.24.1	4 Months
Faeces soft	v.24.1	
Fatigue	v.24.1	273
Feeling abnormal	v.24.1	1 Months
Headache	v.24.1	1 Months
Pain in extremity	v.24.1	4 Days
Staphylococcal infection	v.24.1	0

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04643038	0	2021-09-07	2021-09-07	MAH	202101099084	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
34 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
INSULIN	Concomitant	GLOBULES ORAL					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arnold-Chiari malformation	v.24.1	
Condition aggravated	v.24.1	
Migraine	v.24.1	
Motion sickness	v.24.1	
Muscle spasms	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Nodule	v.24.1	
Pain in extremity	v.24.1	
Swelling	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04643095	0	2021-09-07	2021-09-07	MAH	202101102958	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
45 Years	Female			Recovered/resolved with sequelae

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bell's palsy	v.24.1	1 Months
Eyelid pain	v.24.1	1 Months
Hypoaesthesia	v.24.1	1 Months
Inappropriate schedule of product administration	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04643109	0	2021-09-07	2021-09-07	MAH	202101161973	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
30 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CONCERTA	Concomitant	TABLET (EXTENDED-RELEASE)	Oral				Attention deficit hyperactivity disorder
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain upper	v.24.1	
Haemorrhage	v.24.1	
Inappropriate schedule of product administration	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Menstruation irregular	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04643187	0	2021-09-07	2021-09-07	MAH	202101119047	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
67 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arrhythmia	v.24.1	
Tachycardia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04643189	0	2021-09-07	2021-09-07	MAH	202101109477	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
47 Years	Male			Recovered/resolved with sequelae

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Swelling face	v.24.1	-159

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04643198	0	2021-09-07	2021-09-07	MAH	202101102101	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
33 Years	Male			Recovered/resolved with sequelae

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown			1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Uveitis	v.24.1	
Visual impairment	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04643236	1	2021-09-07	2021-09-08	MAH	2021581149	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.24.1	
Pain in extremity	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04643265	0	2021-09-07	2021-09-07	MAH	202101102412	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
32 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
NAPROXEN	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
TYLENOL	Concomitant	NOT SPECIFIED					
VYVANSE	Concomitant	Capsules					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Lymph node pain	v.24.1	
Lymphadenitis	v.24.1	
Neck pain	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pain in jaw	v.24.1	
Speech disorder	v.24.1	
Swelling face	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04643308	0	2021-09-07	2021-09-07	MAH	202101102213	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
34 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	
Nausea	v.24.1	4 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04644777	0	2021-09-07	2021-09-07	MAH	202101102217	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
43 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Herpes zoster oticus	v.24.1	
Inappropriate schedule of product administration	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04644934	0	2021-09-07	2021-09-07	MAH	2021A714517	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Injection site pain	v.24.1	
Injection site swelling	v.24.1	
Rash	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04645063	0	2021-09-07	2021-09-07	MAH	2021A714608	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
58 Years	Female	163 Centimeter	53 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.5 ml			COVID-19 immunisation
SYNTHROID	Concomitant	NOT SPECIFIED	Unknown				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Burning sensation	v.24.1	
Fatigue	v.24.1	
Muscular weakness	v.24.1	
Musculoskeletal stiffness	v.24.1	
Paraesthesia	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Paraesthesia oral	v.24.1	
Visual impairment	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04645067	0	2021-09-08	2021-09-08	MAH	2021A714631	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
42 Years	Female	165 Centimeter	61 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intravenous (not otherwise specified)				COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Eye pain	v.24.1	
Headache	v.24.1	
Incorrect route of product administration	v.24.1	
Loss of personal independence in daily activities	v.24.1	
Oropharyngeal pain	v.24.1	
Visual impairment	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04645118	0	2021-09-08	2021-09-08	MAH	2021A714740	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
48 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abnormal sensation in eye	v.24.1	
Burning sensation	v.24.1	
Discomfort	v.24.1	
Headache	v.24.1	
Muscle spasms	v.24.1	
Pain in extremity	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04645202	0	2021-09-08	2021-09-08	MAH	2021A714612	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
59 Years	Male	180 Centimeter	81 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.5 ml			Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.24.1	
Dyspnoea	v.24.1	
Headache	v.24.1	
Medication error	v.24.1	
Urticaria	v.24.1	
Vision blurred	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04645226	0	2021-09-08	2021-09-08	MAH	2021A714782	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
43 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.5 ml			COVID-19 immunisation
LORATADINE	Concomitant	NOT SPECIFIED	Unknown				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypersensitivity	v.24.1	1 Days
Paraesthesia	v.24.1	1 Days
Swelling face	v.24.1	1 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04645229	0	2021-09-08	2021-09-08	MAH	2021A714758	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
49 Years	Female	166 Centimeter	62 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.5 ml			COVID-19 immunisation
IRON	Concomitant		Unknown				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Feeling cold	v.24.1	
Personality change	v.24.1	
Sensory disturbance	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:08:27 AM
Initial Received Date:	2021-07-30 to 2021-09-30
Latest Received Date:	N/A
Total Number of Reports:	703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04645295	0	2021-09-08	2021-09-08	MAH	2018SA254304	Study	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AUBAGIO	Suspect	Tablets	Oral	14.0 Milligram	1 every 1 Days		Relapsing-remitting multiple sclerosis, Multiple sclerosis
AUBAGIO	Suspect	Film-coated tablet	Oral	14.0 Milligram	1 every 1 Days		Relapsing-remitting multiple sclerosis, Multiple sclerosis
BIOTIN	Concomitant	NOT SPECIFIED	Unknown	5000.0 Microgram			
CALCIUM	Concomitant	NOT SPECIFIED	Unknown				
CELECOXIB	Concomitant	Capsules	Unknown	100.0 Milligram			

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				COVID-19 immunisation
CYCLOBENZAPRINE	Concomitant		Unknown	10.0 Milligram			
FISH OIL 600 EPA/300 DHA	Concomitant	Capsule	Oral				
GLUCOSAMINE	Concomitant	NOT SPECIFIED	Unknown				
MAGNESIUM	Concomitant	NOT SPECIFIED	Unknown		1 every 2 Days		
MSM	Concomitant	Capsule	Unknown		1 every 2 Days		
MYRBETRIQ	Concomitant	TABLET (EXTENDED-RELEASE)	Unknown	25.0 Milligram	1 every 12 Hours		
OMEGA 3 [FISH OIL]	Concomitant		Unknown				
TYLENOL	Concomitant	NOT SPECIFIED	Unknown				
VITAMIN B 12 [VITAMIN B12 NOS]	Concomitant		Unknown				
VITAMIN C [ASCORBIC ACID]	Concomitant		Unknown				
VITAMIN D	Concomitant	NOT SPECIFIED	Unknown				Multiple sclerosis
VITAMINS NOS	Concomitant		Unknown				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Multiple sclerosis	v.24.1	
Pain	v.24.1	
Therapy interrupted	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:08:27 AM
Initial Received Date:	2021-07-30 to 2021-09-30
Latest Received Date:	N/A
Total Number of Reports:	703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04645318	0	2021-09-08	2021-09-08	MAH	2021A714765	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
43 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.5 ml			Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Immune thrombocytopenia	v.24.1	
Thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04645322	0	2021-09-08	2021-09-08	MAH	2021A714759	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male	180 Centimeter	108 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Full blood count abnormal	v.24.1	
Lethargy	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:08:27 AM
Initial Received Date:	2021-07-30 to 2021-09-30
Latest Received Date:	N/A
Total Number of Reports:	703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04645357	0	2021-09-08	2021-09-08	MAH	2021A714580	Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
43 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Dizziness	v.24.1	
Hyperhidrosis	v.24.1	
Muscle twitching	v.24.1	
Pallor	v.24.1	
Paraesthesia	v.24.1	
Syncope	v.24.1	
Thirst	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Unresponsive to stimuli	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04645602	0	2021-09-08	2021-09-08	MAH	2021A714744	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Herpes zoster	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04645706	0	2021-09-08	2021-09-08	MAH	2021A714635	Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
45 Years	Female		68 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.5 ml			COVID-19 immunisation
FERROUS SULFATE	Concomitant		Unknown				
PRO-AAS EC - 80	Concomitant	TABLET (DELAYED-RELEASE)	Unknown				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Injection site pain	v.24.1	
Muscular weakness	v.24.1	
Myalgia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04645738	0	2021-09-08	2021-09-08	MAH	2021A714775	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
48 Years	Male	177 Centimeter	67 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETAMINOPHEN	Concomitant	NOT SPECIFIED	Unknown				
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.5 ml			COVID-19 immunisation
FINASTERIDE	Concomitant	Tablets	Unknown				
OMEGA - 3 FISH OIL 36/24	Concomitant	Capsules	Unknown				
PANTOPRAZOLE	Concomitant	NOT SPECIFIED	Unknown				
VITAMIN D	Concomitant	NOT SPECIFIED	Unknown				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Blood creatinine decreased	v.24.1	
Cerebellar atrophy	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.24.1	
Dizziness	v.24.1	
Fatigue	v.24.1	
Haemoglobin decreased	v.24.1	
Head injury	v.24.1	
Headache	v.24.1	
Hypovolaemia	v.24.1	
Malaise	v.24.1	
Myalgia	v.24.1	
Pain in extremity	v.24.1	
Presyncope	v.24.1	
Pyrexia	v.24.1	
Sinus bradycardia	v.24.1	
Syncope	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:08:27 AM
Initial Received Date:	2021-07-30 to 2021-09-30
Latest Received Date:	N/A
Total Number of Reports:	703 Report(s)

Report Information

***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04645839	0	2021-09-08	2021-09-08	MAH	2021A714655	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
68 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.5 ml			Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.24.1	
Diarrhoea	v.24.1	
Dizziness	v.24.1	
Fatigue	v.24.1	
Flushing	v.24.1	
Headache	v.24.1	
Hypoaesthesia	v.24.1	
Injection site erythema	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Injection site pain	v.24.1	
Injection site swelling	v.24.1	
Nausea	v.24.1	
Paraesthesia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04645883	0	2021-09-08	2021-09-08	MAH	2021A714675	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
56 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dyspnoea exertional	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04645905	0	2021-09-08	2021-09-08	MAH	2021A714728	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
65 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ADVAIR 250 DISKUS	Concomitant		Unknown				
ALLOPURINOL	Concomitant	Tablets					
AMLODIPINE	Concomitant	Tablets	Unknown				
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.5 ml			Product used for unknown indication
BISOPROLOL	Concomitant						
CANDESARTAN	Concomitant						
CHLORTHALIDONE	Concomitant	Tablets					
ELIQUIS FILM COATED	Concomitant	Tablets					
FINASTERIDE	Concomitant	Tablets					
FUROSEMIDE	Concomitant	NOT SPECIFIED	Unknown				
IRON	Concomitant						

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
LANTUS	Concomitant	SOLUTION SUBCUTANEOUS					
LORAZEPAM	Concomitant	NOT SPECIFIED	Unknown				
MONTELUKAST	Concomitant	NOT SPECIFIED					
NOVORAPID	Concomitant	SOLUTION SUBCUTANEOUS					
OMEPRAZOLE	Concomitant	NOT SPECIFIED					
PREGABALIN	Concomitant	Capsules					
ROSUVASTATIN	Concomitant	NOT SPECIFIED	Unknown				
TAMSULOSIN	Concomitant	NOT SPECIFIED					
TEMAZEPAM	Concomitant	Capsules					
VENTOLIN	Concomitant	NOT SPECIFIED					
VITAMIN B COMPLEX	Concomitant						
VITAMINS NOS	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest discomfort	v.24.1	
Chills	v.24.1	
Confusional state	v.24.1	
Diarrhoea	v.24.1	
Dyspnoea	v.24.1	
Malaise	v.24.1	
Pyrexia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04645937	0	2021-09-08	2021-09-08	MAH	2021A714762	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
59 Years	Male	175 Centimeter	81 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.5 ml		1.0 Days	COVID-19 prophylaxis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dysstasia	v.24.1	
Gait inability	v.24.1	
Neuralgia	v.24.1	
Pain	v.24.1	
Pain in extremity	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04646031	0	2021-09-08	2021-09-08	MAH	2021A714754	Spontaneous	Consumer/other non health professional

Serious report?	Death:	Disability:	Congenital Anomaly:
Serious	Yes	No	No
	Life Threatening: No	**Hospitalization:** No	**Other Medically Important Conditions:** Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
55 Years	Female			Fatal

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Prophylaxis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain	v.24.1	
Abnormal behaviour	v.24.1	
Anxiety	v.24.1	
Aphasia	v.24.1	
Cerebral thrombosis	v.24.1	
Discoloured vomit	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Electric shock sensation	v.24.1	
Headache	v.24.1	
Malaise	v.24.1	
Neurological symptom	v.24.1	
Off label use	v.24.1	
Pain	v.24.1	
Platelet count decreased	v.24.1	
Pulmonary embolism	v.24.1	
Pulmonary infarction	v.24.1	
Speech disorder	v.24.1	
Thrombosis	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04646355	0	2021-09-08	2021-09-08	MAH	2021A716845	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
56 Years	Female	160 Centimeter	66 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
APIXABAN	Concomitant		Unknown				Fibromuscular dysplasia
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.5 ml			Product used for unknown indication
FLUOXETINE HYDROCHLORIDE	Concomitant		Unknown				Major depression

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	3 Days
Headache	v.24.1	3 Days
Nausea	v.24.1	3 Days
Pain	v.24.1	3 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04646423	0	2021-09-08	2021-09-08	MAH	2021A714742	Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
55 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.5 ml			Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Diplopia	v.24.1	5 Days
Eyelid ptosis	v.24.1	5 Days
Headache	v.24.1	5 Days
IIIrd nerve paralysis	v.24.1	
Influenza like illness	v.24.1	5 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04646441	0	2021-09-08	2021-09-08	MAH	2021A714473	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
55 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.5 ml			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Tinnitus	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04646677	0	2021-09-08	2021-09-08	MAH	2021A714359	Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
47 Years	Male		63 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.5 ml			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.24.1	
Contusion	v.24.1	
Fatigue	v.24.1	
Paraesthesia	v.24.1	
Pyrexia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04647002	0	2021-09-08	2021-09-08	MAH	2021A714766	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
59 Years	Female	168 Centimeter	66 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Myalgia	v.24.1	
Periarthritis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04647071	0	2021-09-08	2021-09-08	MAH	2021A716793	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
57 Years	Male	170 Centimeter	108 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.5 ml			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blindness transient	v.24.1	
Transient ischaemic attack	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04647076	0	2021-09-08	2021-09-08	MAH	2021A716854	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
47 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Stevens-Johnson syndrome	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04647082	0	2021-09-08	2021-09-08	MAH	2021A716830	Spontaneous	Consumer/other non health professional

Serious report?	Death:	Disability:	Congenital Anomaly:
Serious	Yes	No	No
	Life Threatening: No	**Hospitalization:** Yes	**Other Medically Important Conditions:** Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Fatal

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.5 ml			Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Thrombocytopenia	v.24.1	
Thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04647193	0	2021-09-08	2021-09-08	MAH	2021A716871	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
76 Years		160 Centimeter	63 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cerebrovascular accident	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:08:27 AM
Initial Received Date:	2021-07-30 to 2021-09-30
Latest Received Date:	N/A
Total Number of Reports:	703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04647746	0	2021-09-08	2021-09-08	MAH	2021A709549	Published	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Capillary leak syndrome	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04648518	0	2021-09-08	2021-09-08	MAH	202101127903	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
30 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CONCERTA	Concomitant	TABLET (EXTENDED-RELEASE)	Oral				Attention deficit hyperactivity disorder
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain upper	v.24.1	
Haemorrhage	v.24.1	
Menstruation irregular	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04648684	0	2021-09-08	2021-09-08	MAH	202101116409	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
49 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CYANOCOBALAMIN	Concomitant		Oral				
DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE/METFORMIN HYDROCHLORIDE	Concomitant		Oral				Diabetes mellitus
GLICLAZIDE	Concomitant		Oral				Diabetes mellitus
PERINDOPRIL	Concomitant		Oral				Hypertension
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
ROSUVASTATIN	Concomitant	NOT SPECIFIED	Oral				Blood cholesterol

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blister	v.24.1	
Condition aggravated	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04648733	0	2021-09-08	2021-09-08	MAH	202101108959	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
29 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
IBUPROFEN	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dental discomfort	v.24.1	
Fatigue	v.24.1	
Intracranial pressure increased	v.24.1	
Nausea	v.24.1	
Pain in extremity	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Sleep disorder	v.24.1	
Visual impairment	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04648974	0	2021-09-08	2021-09-08	MAH	202101126227	Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
78 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
FERROUS FUMARATE	Concomitant	NOT SPECIFIED					
ISONIAZID	Concomitant	NOT SPECIFIED					
LACTULOSE	Concomitant	LIQUID ORAL					
LEVOTHYROXINE SODIUM	Concomitant	NOT SPECIFIED					
METOCLOPRAMIDE	Concomitant						
MIRTAZAPINE	Concomitant	Tablets					
PANTOPRAZOLE	Concomitant	NOT SPECIFIED					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
PYRIDOXINE	Concomitant	NOT SPECIFIED					
RIFABUTIN	Concomitant	NOT SPECIFIED					
VITAMIN D	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Atrial fibrillation	v.24.1	-183
Cardiac failure congestive	v.24.1	-183

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04649443	0	2021-09-08	2021-09-08	MAH	202101110747	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
35 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETAMINOPHEN	Concomitant	NOT SPECIFIED					
IBUPROFEN	Concomitant	NOT SPECIFIED					
MRNA-1273 SARS-COV-2	Suspect	NOT SPECIFIED	Unknown		Total	1.0 Days	COVID-19 immunisation
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anxiety	v.24.1	
Chest discomfort	v.24.1	
Chest pain	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Product use issue	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04649508	0	2021-09-08	2021-09-08	MAH	202101116951	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
36 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown			1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Facial paralysis	v.24.1	
Facial paralysis	v.24.1	
Headache	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Off label use	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:08:27 AM
Initial Received Date:	2021-07-30 to 2021-09-30
Latest Received Date:	N/A
Total Number of Reports:	703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04649779	1	2021-09-08	2021-09-13	MAH	2021BI01045645	Study	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
69 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				COVID-19 prophylaxis
FAMPYRA	Suspect	TABLET (EXTENDED-RELEASE)	Oral	10.0 Milligram	2 every 1 Days		Multiple sclerosis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Drug ineffective	v.24.1	
Temperature intolerance	v.24.1	
Vaccination complication	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04649888	0	2021-09-08	2021-09-08	MAH	2021A716879	Spontaneous	Consumer/other non health professional

Serious report?	Death:	Disability:	Congenital Anomaly:
Serious	Yes	No	No
	Life Threatening: No	**Hospitalization:** No	**Other Medically Important Conditions:** Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Fatal

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Thrombocytopenia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04650131	0	2021-09-09	2021-09-09	MAH	2021A716314	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
51 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Product used for unknown indication
CIALIS	Concomitant	Tablets	Unknown				
DEXEDRINE	Concomitant	NOT SPECIFIED	Unknown	5.0 Milligram			
DOXEPIN HYDROCHLORIDE	Concomitant		Unknown				
LORAZEPAM	Concomitant	NOT SPECIFIED	Unknown				
SERTRALINE HYDROCHLORIDE	Concomitant		Unknown				
VYVANSE	Concomitant	Capsules	Unknown				
ZOLPIDEM	Concomitant		Unknown				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Deafness	v.24.1	
Tinnitus	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04650355	0	2021-09-09	2021-09-09	MAH	2021A716868	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.24.1	
Rash erythematous	v.24.1	
Seizure	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04650724	0	2021-09-09	2021-09-09	MAH	2021A714512	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
54 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.5 ml			Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Migraine	v.24.1	5 Days
Neck pain	v.24.1	5 Days
Stomatitis	v.24.1	5 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:08:27 AM
Initial Received Date:	2021-07-30 to 2021-09-30
Latest Received Date:	N/A
Total Number of Reports:	703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04650852	0	2021-09-09	2021-09-09	MAH	2021A714632	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fall	v.24.1	
Head injury	v.24.1	
Pyrexia	v.24.1	
Skin laceration	v.24.1	
Suture insertion	v.24.1	
Syncope	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04651440	1	2021-09-09	2021-10-21	MAH	202101133658	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blindness unilateral	v.24.1	
Paraesthesia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:08:27 AM
Initial Received Date:	2021-07-30 to 2021-09-30
Latest Received Date:	N/A
Total Number of Reports:	703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04651519	0	2021-09-09	2021-09-09	MAH	202101116076	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
35 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Adnexa uteri pain	v.24.1	
Fatigue	v.24.1	
Headache	v.24.1	
Heavy menstrual bleeding	v.24.1	
Insomnia	v.24.1	
Menstrual disorder	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Menstrual disorder	v.24.1	
Nausea	v.24.1	
Premenstrual syndrome	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04652088	0	2021-09-09	2021-09-09	MAH	202101127857	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
41 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
DIANE-35	Concomitant	Tablets					
FINASTERIDE	Concomitant	Tablets					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
SPIRONOLACTONE	Concomitant	Tablets					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain upper	v.24.1	
Angina pectoris	v.24.1	
Headache	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pain in extremity	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:08:27 AM
Initial Received Date:	2021-07-30 to 2021-09-30
Latest Received Date:	N/A
Total Number of Reports:	703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04652263	0	2021-09-09	2021-09-09	MAH	202101128686	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
38 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cardiac discomfort	v.24.1	
Chest discomfort	v.24.1	
Chills	v.24.1	
Dyspnoea	v.24.1	
Fatigue	v.24.1	
Heart rate decreased	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Migraine	v.24.1	
Pain	v.24.1	
Pain in extremity	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04652541	0	2021-09-09	2021-09-09	MAH	2021A714773	Spontaneous	Pharmacist

Serious report?	Death:	Yes	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
54 Years	Female	160 Centimeter	68 Kilogram	Fatal

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				COVID-19 prophylaxis
METFORMIN/SITAGLIPTIN E	Concomitant		Unknown				
TYLENOL	Concomitant	NOT SPECIFIED	Unknown				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cerebral haemorrhage	v.24.1	
Cerebral venous thrombosis	v.24.1	
Cerebrovascular accident	v.24.1	
Coagulopathy	v.24.1	
Decompressive craniectomy	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	
Headache	v.24.1	
Immune thrombocytopenia	v.24.1	
Nausea	v.24.1	
Platelet transfusion	v.24.1	
Thrombectomy	v.24.1	
Venous hypertension	v.24.1	
Vision blurred	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04652542	0	2021-09-09	2021-09-09	MAH	2021A716864	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
54 Years	Female	152 Centimeter	54 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypoaesthesia	v.24.1	
Paraesthesia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04652642	0	2021-09-09	2021-09-09	MAH	2021A716288	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
67 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cerebral infarction	v.24.1	
Cervical vertebral fracture	v.24.1	
Coma scale abnormal	v.24.1	
Decerebrate posture	v.24.1	
Depressed level of consciousness	v.24.1	
Failure to thrive	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Intracranial aneurysm	v.24.1	
Respiratory distress	v.24.1	
Vascular injury	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04653408	0	2021-09-09	2021-09-09	MAH	2021574793	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
28 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
DOXYCYCLINE	Concomitant	NOT SPECIFIED	Oral	100.0 Milligram	every 1 Days		
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.24.1	
Angioedema	v.24.1	
Diarrhoea	v.24.1	
Erythema	v.24.1	
Inappropriate schedule of product administration	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Loss of consciousness	v.24.1	
Mechanical urticaria	v.24.1	
Paraesthesia	v.24.1	
Pruritus	v.24.1	
Sensitive skin	v.24.1	
Shock	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04653579	0	2021-09-09	2021-09-09	MAH	202101116481	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown				COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Adverse event	v.24.1	
Dental discomfort	v.24.1	
Gingival discomfort	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Oedema peripheral	v.24.1	
Pneumonia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04655159	1	2021-09-10	2021-09-10	MAH	MOD-2021-307755	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	1.0 Dosage forms			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Lyme disease	v.24.1	
Vaccination site pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04655734	0	2021-09-10	2021-09-10	MAH	MOD-2021-307645	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	1.0 Dosage forms			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Lyme disease	v.24.1	
Vaccination site reaction	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04655747	0	2021-09-10	2021-09-10	MAH	2021A716865	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
41 Years	Female	158 Centimeter	83 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ADRENAL-PRO	Concomitant						
ALGAE/NICOTINAMIDE/PANTOTHENIC ACID/PYRIDOXINE/RIBOFLAVIN/SELENIUM/THIAMINE/TYROSINE/VITAMIN B12	Concomitant						
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.5 ml			COVID-19 immunisation
MAGNESIUM	Concomitant	NOT SPECIFIED	Unknown				
PEAK PERFORMANCE BONE & JOINT PACK WOMEN'S (VITALITY MULTIVITAMIN &...	Concomitant						

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
THYROID	Concomitant	Tablet					
THYROID-PRO FORMULA	Concomitant						
VITAMIN C	Concomitant	NOT SPECIFIED					
VITAMIN D	Concomitant	Capsules	Unknown				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dysmenorrhoea	v.24.1	13 Days
Intermenstrual bleeding	v.24.1	13 Days
Thrombosis	v.24.1	13 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04656258	0	2021-09-10	2021-09-10	MAH	MOD-2021-304857	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Unknown	1.0 Dosage forms			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bell's palsy	v.24.1	
Interchange of vaccine products	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04657015	0	2021-09-10	2021-09-10	MAH	202101133934	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
46 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic shock	v.24.1	
Dyspnoea	v.24.1	
Pharyngeal swelling	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04657040	0	2021-09-10	2021-09-10	MAH	202101137554	Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
72 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.24.1	
Cough	v.24.1	
Dyspnoea	v.24.1	
Lethargy	v.24.1	
Neurological symptom	v.24.1	
Pulmonary embolism	v.24.1	
Pyrexia	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Rhinorrhoea	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04657101	0	2021-09-10	2021-09-10	MAH	202101162606	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
39 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain	v.24.1	
Asthenia	v.24.1	
Cardiac infection	v.24.1	
Chest pain	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Palpitations	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pericarditis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:08:27 AM
Initial Received Date:	2021-07-30 to 2021-09-30
Latest Received Date:	N/A
Total Number of Reports:	703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04657133	0	2021-09-10	2021-09-10	MAH	2021635861	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
28 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.24.1	
Hypoaesthesia	v.24.1	
Migraine	v.24.1	
Paraesthesia	v.24.1	
Sensory disturbance	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04657136	0	2021-09-10	2021-09-10	MAH	202101133870	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
30 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Heavy menstrual bleeding	v.24.1	9 Days
Inappropriate schedule of product administration	v.24.1	
Off label use	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:08:27 AM
Initial Received Date:	2021-07-30 to 2021-09-30
Latest Received Date:	N/A
Total Number of Reports:	703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04657189	0	2021-09-10	2021-09-10	MAH	202101064364	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
28 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Ear pain	v.24.1	
Headache	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Oropharyngeal pain	v.24.1	
Sinus headache	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04657427	0	2021-09-10	2021-09-10	MAH	202101127878	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
38 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BIPHENTIN	Concomitant	CAPSULE, EXTENDED RELEASE					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
TRAZODONE	Concomitant						
VENTOLINE [SALBUTAMOL]	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Back pain	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bone pain	v.24.1	
Presyncope	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:08:27 AM
Initial Received Date:	2021-07-30 to 2021-09-30
Latest Received Date:	N/A
Total Number of Reports:	703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04657440	0	2021-09-10	2021-09-10	MAH	202101118149	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
82 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
INDAPAMIDE	Concomitant	Tablets					
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
SYNTHROID	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Erythema multiforme	v.24.1	
Inappropriate schedule of product administration	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04658476	0	2021-09-13	2021-09-13	MAH	MOD-2021-312137	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
28 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Unknown	1.0 Dosage forms			COVID-19 immunisation
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	Injection	Intramuscular	1.0 Dosage forms			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Balance disorder	v.24.1	
Feeling abnormal	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Feeling cold	v.24.1	1 Days
Joint stiffness	v.24.1	
Loss of consciousness	v.24.1	
Muscle tightness	v.24.1	
Myalgia	v.24.1	
Pain in extremity	v.24.1	
Seizure	v.24.1	
Tremor	v.24.1	1 Days
Vaccination error	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04660219	0	2021-09-13	2021-09-13	MAH	202101128014	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
14 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Angina pectoris	v.24.1	-199
Back pain	v.24.1	-199
Chest pain	v.24.1	-199
Dizziness	v.24.1	-199
Dyspnoea	v.24.1	-199
Injection site swelling	v.24.1	-199

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Insomnia	v.24.1	-199
Migraine	v.24.1	-199
Nausea	v.24.1	-199
Palpitations	v.24.1	-199
Vision blurred	v.24.1	-199

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04660652	0	2021-09-13	2021-09-13	MAH	2021A718827	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
60 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood glucose increased	v.24.1	
Diabetes mellitus inadequate control	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04660706	0	2021-09-13	2021-09-13	MAH	2021A716919	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				COVID-19 prophylaxis
ELIGARD	Suspect	POWDER FOR SUSPENSION, SUSTAINED-RELEASE	Subcutaneous	22.5 Milligram	1 every 3 Months		Prostate cancer

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Confusional state	v.24.1	
Fatigue	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Gait disturbance	v.24.1	
Gastric dilatation	v.24.1	
General physical health deterioration	v.24.1	
Oedema peripheral	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04660844	0	2021-09-13	2021-09-13	MAH	2021A716931	Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
56 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.5 ml			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Movement disorder	v.24.1	
Pain in extremity	v.24.1	
Tendonitis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04660859	0	2021-09-13	2021-09-13	MAH	2021A718718	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
51 Years				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Condition aggravated	v.24.1	
Fatigue	v.24.1	
Injection site pain	v.24.1	
Pain	v.24.1	
Tinnitus	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04661899	0	2021-09-13	2021-09-13	MAH	202100985783	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
28 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abnormal sensation in eye	v.24.1	
Arthralgia	v.24.1	
Chest pain	v.24.1	
Costochondritis	v.24.1	
Ear discomfort	v.24.1	
Ear discomfort	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Head discomfort	v.24.1	
Headache	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Lymphadenopathy	v.24.1	
Mass	v.24.1	
Oropharyngeal pain	v.24.1	
Pain in extremity	v.24.1	
Pain in extremity	v.24.1	
Paraesthesia	v.24.1	
Pyrexia	v.24.1	
Swollen tongue	v.24.1	
Tinnitus	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04661987	1	2021-09-13	2021-09-15	MAH	2021640301	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
48 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACLIDINIUM BROMIDE	Concomitant		Intra-nasal				Asthma
CETIRIZINE HYDROCHLORIDE	Concomitant		Oral		1 every 1 Days		Hypersensitivity
FORMOTEROL FUMARATE/MOMETASONE FUROATE	Concomitant		Intra-nasal				Asthma
LOLO	Concomitant	Tablets	Oral				Contraception
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
SINGULAIR	Concomitant	NOT SPECIFIED	Intra-nasal				Asthma

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Condition aggravated	v.24.1	
Heavy menstrual bleeding	v.24.1	
Incorrect product administration duration	v.24.1	
Lipoma	v.24.1	
Oligomenorrhoea	v.24.1	2 Weeks
Rosacea	v.24.1	
Vaccination site oedema	v.24.1	
Vaccination site reaction	v.24.1	
Vaccination site ulcer	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04662037	0	2021-09-13	2021-09-13	MAH	202101128018	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
35 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Decreased appetite	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Lower respiratory tract infection	v.24.1	
Oropharyngeal pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04663576	0	2021-09-13	2021-09-13	MAH	202101137563	Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
12 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.24.1	
Loss of consciousness	v.24.1	
Syncope	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04663622	0	2021-09-13	2021-09-13	MAH	202101133061	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
53 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthma	v.24.1	45 Minutes
Dyspnoea	v.24.1	
Fatigue	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04663868	0	2021-09-13	2021-09-13	MAH	MOD-2021-307715	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	2.0 Dosage forms			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Lyme disease	v.24.1	
Vaccination site pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:08:27 AM
Initial Received Date:	2021-07-30 to 2021-09-30
Latest Received Date:	N/A
Total Number of Reports:	703 Report(s)

Report Information

***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04664373	0	2021-09-13	2021-09-13	MAH	202101126778	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
26 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
DIPHTHERIA TOXOID ADSORBED/PERTUSSIS VACCINE ACELLULAR 5-COMPONENT/TETANUS TOXOID	Concomitant		Intramuscular			1.0 Days	
MINERALS NOS/VITAMINS NOS	Concomitant		Oral				Pregnancy
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Exposure during pregnancy	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Inappropriate schedule of product administration	v.24.1	
Off label use	v.24.1	
Pain in extremity	v.24.1	1 Days
Streptococcal urinary tract infection	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04666754	0	2021-09-14	2021-09-14	MAH	MOD-2021-309221	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
33 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	1.0 Dosage forms			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Angioedema	v.24.1	
Condition aggravated	v.24.1	
Eye swelling	v.24.1	
Pain	v.24.1	
Urticaria	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04667132	0	2021-09-14	2021-09-14	MAH	2021702160	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
26 Years	Female	167 Centimeter	69 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
VITAMINS NOS	Concomitant		Oral	1.0 Dosage forms	every 1 Days		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Maternal exposure during pregnancy	v.24.1	
Streptococcal urinary tract infection	v.24.1	
Vaccination site pain	v.24.1	24 Hours

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04667148	0	2021-09-14	2021-09-14	MAH	202101127183	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
36 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Aphonia	v.24.1	
Balance disorder	v.24.1	
Chest pain	v.24.1	
Cough	v.24.1	
Deafness bilateral	v.24.1	
Dyspnoea	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	
Head discomfort	v.24.1	
Incorrect dose administered	v.24.1	
Insomnia	v.24.1	
Myalgia	v.24.1	
Overdose	v.24.1	
Paranasal sinus discomfort	v.24.1	
Pharyngeal swelling	v.24.1	
Vertigo	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04667709	0	2021-09-14	2021-09-14	MAH	202101137549	Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
60 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Seizure	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04667907	0	2021-09-14	2021-09-14	MAH	202101126501	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
30 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypoaesthesia	v.24.1	
Inappropriate schedule of product administration	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04668243	1	2021-09-14	2021-11-08	MAH	2020SA108467	Study	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
19 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BETADERM	Concomitant	NOT SPECIFIED	Unknown				
BETADERM [BETAMETHASONE DIPROPIONATE;GENTAMICIN SULFATE]	Concomitant		Topical		1 every 1 Days		Dermatitis atopic
CICLOSPORIN	Concomitant	NOT SPECIFIED	Unknown				
CIPRALEX [ESCITALOPRAM]	Concomitant		Oral	10.0 Milligram	1 every 1 Days		
CITALOPRAM HYDROCHLORIDE	Concomitant		Unknown				
COVID-19 VACCINE	Suspect		Unknown				COVID-19 immunisation
DROSPIRENONE/ETHINYL ESTRADIOL	Concomitant		Oral		1 every 1 Days		Oral contraception

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
DUPIXENT	Suspect	Solution for injection	Subcutaneous	300.0 Milligram	1 every 2 Weeks		Dermatitis atopic
DUPIXENT	Suspect	Solution	Subcutaneous	600.0 Milligram	Total	1.0 Days	Dermatitis atopic
METHOTREXATE	Concomitant	NOT SPECIFIED	Unknown				
TACROLIMUS	Concomitant	Capsules	Unknown				
TACROLIMUS MONOHYDRATE	Concomitant		Topical		1 every 1 Days		Dermatitis atopic
TOPICORT [DESOXIMETASONE]	Concomitant		Unknown				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Drug ineffective	v.24.1	
Pericarditis	v.24.1	0
Quality of life decreased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:08:27 AM
Initial Received Date:	2021-07-30 to 2021-09-30
Latest Received Date:	N/A
Total Number of Reports:	703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04669377	0	2021-09-14	2021-09-14	MAH	2021665464	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
45 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BIOTIN	Concomitant	NOT SPECIFIED					
CYANOCOBALAMIN	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
VITAMIN C [ASCORBIC ACID]	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dysstasia	v.24.1	
Gait disturbance	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hemiparesis	v.24.1	
Muscle spasms	v.24.1	
Musculoskeletal pain	v.24.1	
Scoliosis	v.24.1	
Sitting disability	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04669388	0	2021-09-14	2021-09-14	MAH	2021583322	Spontaneous	Physician

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
59 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anxiety	v.24.1	
Dizziness	v.24.1	
Feeling abnormal	v.24.1	-105
Head discomfort	v.24.1	
Headache	v.24.1	
Inflammation	v.24.1	
Insomnia	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Nervous system disorder	v.24.1	
Pain	v.24.1	
Paraesthesia	v.24.1	
Tinnitus	v.24.1	
Tremor	v.24.1	
Vaccination site pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04669441	0	2021-09-14	2021-09-14	MAH	202101137530	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
24 Years	Female			Recovered/resolved with sequelae

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CITALOPRAM	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Diarrhoea	v.24.1	3 Days
Dysmenorrhoea	v.24.1	
Heavy menstrual bleeding	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Menstruation irregular	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Nausea	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04669463	1	2021-09-14	2021-09-24	MAH	202101145997	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
35 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypersensitivity	v.24.1	
Inappropriate schedule of product administration	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04672084	0	2021-09-15	2021-09-15	MAH	202101138882	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
81 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Muscle rupture	v.24.1	
Periarthritis	v.24.1	
Seizure	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04672479	0	2021-09-15	2021-09-15	MAH	202101151415	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
33 Years	Male			Recovered/resolved with sequelae

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bell's palsy	v.24.1	9 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04674200	0	2021-09-15	2021-09-15	MAH	202101138890	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
81 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Inappropriate schedule of product administration	v.24.1	
Off label use	v.24.1	
Periarthritis	v.24.1	
Seizure	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04674270	0	2021-09-15	2021-09-15	MAH	202101190832	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
48 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACLIDINIUM BROMIDE	Concomitant		Inhalation				Asthma
CETIRIZINE HYDROCHLORIDE	Concomitant		Oral		1 every 1 Days		Hypersensitivity
FORMOTEROL FUMARATE/MOMETASONE FUROATE	Concomitant		Inhalation				Asthma
LOLO	Concomitant	Tablets					Contraception
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total	1.0 Days	COVID-19 immunisation
SINGULAIR	Concomitant	NOT SPECIFIED	Inhalation				Asthma

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Condition aggravated	v.24.1	
Heavy menstrual bleeding	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Myalgia	v.24.1	
Neck pain	v.24.1	
Oligomenorrhoea	v.24.1	
Rosacea	v.24.1	
Vaccination site reaction	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04675248	0	2021-09-16	2021-09-16	MAH	MOD-2021-313019	Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	Yes	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
62 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Unknown	1.0 Dosage forms			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cerebrovascular accident	v.24.1	
Product dose omission issue	v.24.1	1 Days
Venous thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04675536	0	2021-09-16	2021-09-16	MAH	2021A725828	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
51 Years	Female	168 Centimeter	59 Kilogram	Recovered/resolved with sequelae

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.5 ml			Product used for unknown indication
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular	0.5 ml			Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Macular hole	v.24.1	2 Months

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04676590	0	2021-09-16	2021-09-16	MAH	2021A724701	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
65 Years	Female	168 Centimeter	68 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Product used for unknown indication
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Intramuscular				Product used for unknown indication
VITAMINS NOS	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Eye inflammation	v.24.1	
Headache	v.24.1	
Myalgia	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Skin tightness	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04676846	0	2021-09-16	2021-09-16	MAH	202101137729	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
48 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Thrombosis	v.24.1	
Vaginal haemorrhage	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04676856	0	2021-09-16	2021-09-16	MAH	202101160678	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_04678855
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Months	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain upper	v.24.1	
Adnexa uteri pain	v.24.1	
Heavy menstrual bleeding	v.24.1	
Menstrual disorder	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04678249	0	2021-09-16	2021-09-16	MAH	202101169174	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
46 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Erythema	v.24.1	
Feeling hot	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Pruritus	v.24.1	
Pyrexia	v.24.1	
Rash	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Urticaria	v.24.1	
Uterine leiomyoma	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04678436	0	2021-09-16	2021-09-16	MAH	202101168810	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
27 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dyspnoea	v.24.1	
Ear infection	v.24.1	
Hypoaesthesia	v.24.1	
Nausea	v.24.1	
Sinusitis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04678452	1	2021-09-16	2021-10-19	MAH	202101162158	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
54 Years	Female		46 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown		Total	1.0 Months	COVID-19 immunisation
INFLIXIMAB	Concomitant		Intravenous (not otherwise specified)	10.0 mg/kg			Colitis ulcerative
PREDNISONE	Concomitant	NOT SPECIFIED	Oral	40.0 Milligram			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
C-reactive protein increased	v.24.1	
Colitis ulcerative	v.24.1	
Diarrhoea haemorrhagic	v.24.1	
Haematochezia	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Mucous stools	v.24.1	
Pyrexia	v.24.1	
Weight decreased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04678767	0	2021-09-16	2021-09-16	MAH	2021A724700	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
65 Years	Female	168 Centimeter	68 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASTRAZENECA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Product used for unknown indication
VITAMINS NOS	Concomitant		Unknown				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Eye inflammation	v.24.1	
Headache	v.24.1	3 Days
Hypoaesthesia	v.24.1	
Influenza like illness	v.24.1	3 Days
Myalgia	v.24.1	3 Days

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Nausea	v.24.1	3 Days
Pyrexia	v.24.1	3 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04678826	0	2021-09-16	2021-09-16	MAH	2021580845	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
33 Years	Female	130 Centimeter	99 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETYLSALICYLIC ACID	Concomitant		Oral		1 every 1 Days		Prophylaxis
DIPHTHERIA TOXOID ADSORBED/PERTUSSIS VACCINE/TETANUS TOXOID	Concomitant		Intramuscular		Total	1.0 Days	
MINERALS NOS/VITAMINS NOS	Concomitant		Oral				Pregnancy
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.3 ml	Total	1.0 Days	COVID-19 immunisation
VITAMIN D	Concomitant		Oral				Pre-eclampsia
VITAMINS NOS	Concomitant		Oral		1 every 1 Days		Pregnancy

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Maternal exposure during pregnancy	v.24.1	
Thrombophlebitis	v.24.1	
Vaccination site pain	v.24.1	-105

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04678855	0	2021-09-16	2021-09-16	MAH	202101160713	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_04676856

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain upper	v.24.1	
Adnexa uteri pain	v.24.1	
Genital pain	v.24.1	
Heavy menstrual bleeding	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Menstrual disorder	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04678864	0	2021-09-16	2021-09-16	MAH	202101145953	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Diarrhoea	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:08:27 AM
Initial Received Date:	2021-07-30 to 2021-09-30
Latest Received Date:	N/A
Total Number of Reports:	703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04680645	0	2021-09-17	2021-09-17	MAH	MOD-2021-314602	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
65 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE MODERNA VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect		Unknown	1.0 Dosage forms			COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Haemorrhage	v.24.1	
Pain in extremity	v.24.1	
Peripheral swelling	v.24.1	
Petit mal epilepsy	v.24.1	
Presyncope	v.24.1	
Weight increased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04681351	0	2021-09-17	2021-09-17	MAH	202101151733	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
62 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
LEVOTHYROXINE SODIUM	Concomitant	NOT SPECIFIED					
PERINDOPRIL	Concomitant						
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation
SERTRALINE HYDROCHLORIDE	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Back pain	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Neck pain	v.24.1	
Pain in extremity	v.24.1	
Thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04681454	0	2021-09-17	2021-09-17	MAH	202101197454	Spontaneous	Consumer/other non health professional

Serious report?	Death:	Yes	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
16 Years	Male			Fatal

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Death	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04683744	0	2021-09-17	2021-09-17	MAH	202101152451	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
58 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total	1.0 Days	COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Electric shock sensation	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Insomnia	v.24.1	
Peripheral swelling	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04687350	2	2021-09-20	2021-11-19	MAH	2889454	Study	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
42 Years	Female		94 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETAZOLAMIDE	Concomitant	NOT SPECIFIED					
ACTEMRA	Suspect	NOT SPECIFIED	Intravenous (not otherwise specified)	715.0 Milligram	1 every 4 Weeks		Rheumatoid arthritis
ALIGN	Concomitant						
AMLODIPINE	Concomitant	Tablets	Unknown				
BLEXTEN	Concomitant	NOT SPECIFIED	Oral				
BUDESONIDE/FORMOTEROL FUMARATE	Concomitant						
CETIRIZINE	Concomitant						
COVID-19 VACCINE	Suspect		Intramuscular				Product used for unknown indication

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ETHINYL ESTRADIOL/LEVONORGESTREL	Concomitant						
HYDROMORPH CONTIN	Concomitant	CAPSULE, SUSTAINED-RELEASE					
HYDROMORPHONE	Concomitant	NOT SPECIFIED					
MONTELUKAST	Concomitant	NOT SPECIFIED					
PREDNISOLONE	Concomitant	NOT SPECIFIED	Ophthalmic				
PREDNISONE	Concomitant	NOT SPECIFIED					
RIZATRIPTAN	Concomitant	NOT SPECIFIED					
SIMBRINZA	Concomitant	SUSPENSION OPHTHALMIC	Ophthalmic				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Angina pectoris	v.24.1	
Arthralgia	v.24.1	
Blood pressure diastolic increased	v.24.1	
Dizziness	v.24.1	
Dizziness	v.24.1	4 Days
Dysstasia	v.24.1	
Fatigue	v.24.1	4 Days
Migraine	v.24.1	
Migraine	v.24.1	
Nausea	v.24.1	
Nausea	v.24.1	
Pain	v.24.1	
Pain in extremity	v.24.1	
Vomiting	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04688003	0	2021-09-20	2021-09-20	MAH	202101167918	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
49 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
FLOVENT	Concomitant	NOT SPECIFIED	Unknown				
HYDROXYCHLOROQUINE SULFATE	Concomitant		Unknown				
ORENCIA	Suspect		Subcutaneous	125.0 Milligram	1 every 1 Weeks		Rheumatoid arthritis
ROSUVASTATIN	Concomitant	NOT SPECIFIED	Unknown				
SYNTHROID	Concomitant	NOT SPECIFIED	Unknown				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cellulitis	v.24.1	
Myalgia	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Oral herpes	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04688031	0	2021-09-20	2021-09-20	MAH	202101167966	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
68 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
IMMUNOGLOBULIN (HUMAN)	Suspect		Unknown	8.0 Gram	1 every 1 Weeks		Secondary immunodeficiency

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Blood pressure decreased	v.24.1	
Blood pressure increased	v.24.1	
Chills	v.24.1	
Diarrhoea	v.24.1	
Nausea	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pyrexia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04689493	0	2021-09-20	2021-09-20	MAH	202101167834	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
50 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AMLODIPINE BESILATE;TELMISARTAN	Concomitant						
CORTEF [HYDROCORTISONE]	Concomitant			5.0 Milligram	2 every 1 Days		
CORTEF [HYDROCORTISONE]	Concomitant			10.0 Milligram			
CORTEF [HYDROCORTISONE]	Concomitant			2.5 Milligram			
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
CYCLOBENZAPRINE	Concomitant						
DESMOPRESSIN	Concomitant						
LANREOTIDE ACETATE	Suspect		Subcutaneous	120.0 Milligram			Acromegaly
OXAZEPAM	Concomitant	Tablets					
PANTOPRAZOLE	Concomitant	NOT SPECIFIED					

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
SYNTHROID	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Discomfort	v.24.1	15 Minutes
Disease progression	v.24.1	
Drug ineffective	v.24.1	
Fatigue	v.24.1	1 Days
Hot flush	v.24.1	
Malaise	v.24.1	
Nasopharyngitis	v.24.1	
Suspected COVID-19	v.24.1	
Vaccination site pain	v.24.1	1 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04689506	0	2021-09-20	2021-09-20	MAH	202101167869	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BUDESONIDE/FORMOTEROL FUMARATE	Suspect	NOT SPECIFIED	Unknown				Product used for unknown indication
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
MEPOLIZUMAB	Suspect		Subcutaneous	100.0 Milligram			Asthma

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Appendicitis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04693820	1	2021-09-21	2021-11-11	MAH	202101167835	Study	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
83 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_04825894

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
HUMIRA	Suspect	SOLUTION SUBCUTANEOUS	Unknown				Product used for unknown indication
MEPOLIZUMAB	Suspect		Subcutaneous	100.0 Milligram			Asthma

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Breast cancer	v.24.1	
Drug hypersensitivity	v.24.1	
Eye disorder	v.24.1	
Eye pain	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Eye swelling	v.24.1	
Hypersensitivity	v.24.1	
Lacrimation increased	v.24.1	
Pyrexia	v.24.1	
Sepsis	v.24.1	4 Days
Swelling face	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04694016	1	2021-09-21	2021-11-11	MAH	202101167898	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
64 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_04825896

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
MEPOLIZUMAB	Suspect		Subcutaneous	100.0 Milligram			Asthma

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Back injury	v.24.1	
Back pain	v.24.1	
Drug ineffective	v.24.1	
Dyspnoea exertional	v.24.1	
Fall	v.24.1	
Gait disturbance	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Lumbar vertebral fracture	v.24.1	
Pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04694208	0	2021-09-21	2021-09-21	MAH	202101167937	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
54 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ATARAX [HYDROXYZINE]	Concomitant		Unknown				
BETADERM	Concomitant	NOT SPECIFIED	Unknown				
CETIRIZINE HYDROCHLORIDE	Concomitant		Unknown				
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
DUPILUMAB	Suspect		Subcutaneous	300.0 Milligram			Dermatitis atopic
TACROLIMUS	Concomitant	Capsules	Unknown				
VENTOLINE [SALBUTAMOL]	Concomitant		Unknown				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.24.1	1 Months
Fatigue	v.24.1	1 Months
Hyperhidrosis	v.24.1	1 Months
Loss of consciousness	v.24.1	1 Days
Scratch	v.24.1	1 Months

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04694236	0	2021-09-21	2021-09-21	MAH	202101167912	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
73 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_04825902
Linked	E2B_04825902

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
MEPOLIZUMAB	Suspect		Subcutaneous	100.0 Milligram			Asthma

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Balance disorder	v.24.1	
Chronic obstructive pulmonary disease	v.24.1	
Deafness	v.24.1	
Depression	v.24.1	
Dry skin	v.24.1	
Dyspnoea	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Ill-defined disorder	v.24.1	
Neoplasm malignant	v.24.1	
Pain	v.24.1	
Product dose omission issue	v.24.1	
Productive cough	v.24.1	
Rash	v.24.1	
Renal cancer	v.24.1	
Therapeutic product effect incomplete	v.24.1	
Tinnitus	v.24.1	
Tooth disorder	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04696398	2	2021-09-22	2021-10-29	MAH	20210925160	Study	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
40 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				Immunisation
SIMPONI	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypotension	v.24.1	
Malaise	v.24.1	
Pyrexia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:08:27 AM
Initial Received Date:	2021-07-30 to 2021-09-30
Latest Received Date:	N/A
Total Number of Reports:	703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04699397	1	2021-09-22	2021-09-29	MAH	2106CAN007687	Study	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
60 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				Prophylaxis
PEMBROLIZUMAB	Suspect	Solution for injection	Unknown				Microsatellite instability cancer, Colorectal cancer metastatic, Colorectal adenocarcinoma

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PEMBROLIZUMAB	Suspect	Solution for injection	Unknown	200.0 Milligram	1 every 3 Weeks		Microsatellite instability cancer, Colorectal cancer metastatic, Colorectal adenocarcinoma
PEMBROLIZUMAB	Suspect		Unknown	200.0 Milligram	1 every 3 Weeks	0.0	Microsatellite instability cancer, Colorectal cancer metastatic, Colorectal adenocarcinoma

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal mass	v.24.1	
Alanine aminotransferase decreased	v.24.1	
Anxiety	v.24.1	
Arthralgia	v.24.1	
Arthropod sting	v.24.1	
Aspartate aminotransferase decreased	v.24.1	
Asthenia	v.24.1	
Blood creatinine abnormal	v.24.1	
Blood thyroid stimulating hormone decreased	v.24.1	
Carcinoembryonic antigen decreased	v.24.1	
Decreased appetite	v.24.1	
Depressed mood	v.24.1	
Fatigue	v.24.1	
General physical health deterioration	v.24.1	
Haemoglobin abnormal	v.24.1	
Haemorrhoids	v.24.1	
Headache	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hepatic enzyme abnormal	v.24.1	
Hypothyroidism	v.24.1	
Lymphocyte count abnormal	v.24.1	
Mean cell volume abnormal	v.24.1	
Monocyte count abnormal	v.24.1	
Neutrophil count abnormal	v.24.1	
Platelet count abnormal	v.24.1	
Pyrexia	v.24.1	
Red blood cell count abnormal	v.24.1	
Renal failure	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04699604	0	2021-09-22	2021-09-22	MAH	202101176649	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
72 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AMOXICILLIN	Concomitant	NOT SPECIFIED	Unknown	500.0 Milligram	3 every 1 Days		
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
IMMUNOGLOBULIN (HUMAN)	Suspect		Subcutaneous	8.0 Gram	1 every 1 Weeks		Secondary immunodeficiency

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal discomfort	v.24.1	
Fatigue	v.24.1	
Gait disturbance	v.24.1	
Infection	v.24.1	
Joint swelling	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Malaise	v.24.1	
Pain	v.24.1	
Renal disorder	v.24.1	
Sinusitis	v.24.1	
Therapeutic product ineffective	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04699605	0	2021-09-22	2021-09-22	MAH	202101028216	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
78 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Duplicate	E2B_04567208

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETYLSALICYLIC ACID	Concomitant	NOT SPECIFIED	Unknown				
ALLOPURINOL	Concomitant	Tablets					
ALLOPURINOL	Concomitant						
CANDESARTAN	Concomitant						
CLOPIDOGREL	Concomitant	Tablets					
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
ESBRIET	Suspect		Oral	267.0 Milligram	3 every 1 Days	31.0 Days	Idiopathic pulmonary fibrosis
ESBRIET	Suspect	Tablet	Oral	534.0 Milligram	3 every 1 Days		Idiopathic pulmonary fibrosis

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ESBRIET	Suspect	Capsules	Oral	801.0 Milligram	3 every 1 Days	365.0 Days	Idiopathic pulmonary fibrosis
GLICLAZIDE	Concomitant	Tablets					
LIPITOR	Concomitant	NOT SPECIFIED	Unknown				
METFORMIN HYDROCHLORIDE/SITAGLIPTIN PHOSPHATE MONOHYDRATE	Concomitant						
PANTOPRAZOLE	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal discomfort	v.24.1	
Arterial occlusive disease	v.24.1	
Cardiac failure congestive	v.24.1	
Coronary artery occlusion	v.24.1	
Dyspnoea	v.24.1	
Dyspnoea	v.24.1	
Idiopathic pulmonary fibrosis	v.24.1	
Urine flow decreased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04699607	0	2021-09-22	2021-09-22	MAH	202101176567	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
57 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
MEPOLIZUMAB	Suspect		Subcutaneous	100.0 Milligram			Asthma

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chronic obstructive pulmonary disease	v.24.1	
Illness	v.24.1	
Immune system disorder	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Nasopharyngitis	v.24.1	
Pneumonia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04699613	1	2021-09-22	2021-12-21	MAH	202101176824	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
71 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BUDESONIDE/FORMOTEROL	Concomitant		Unknown				
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
MEPOLIZUMAB	Suspect	Powder for injection	Subcutaneous	100.0 Milligram			Asthma
MEPOLIZUMAB	Suspect		Subcutaneous	100.0 Milligram			Asthma
METFORMIN	Concomitant		Unknown				
MONTELUKAST SODIUM	Concomitant		Unknown				
PANTOPRAZOLE	Concomitant	NOT SPECIFIED	Unknown				
SPIRIVA	Concomitant	NOT SPECIFIED	Unknown				
VENTOLIN [SALBUTAMOL]	Concomitant		Unknown				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthmatic crisis	v.24.1	
Blood glucose increased	v.24.1	
Dyspnoea exertional	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04699614	1	2021-09-22	2021-11-11	MAH	202101176820	Study	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
43 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_04819813

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
OCRELIZUMAB	Suspect		Intravenous (not otherwise specified)	300.0 Milligram			Relapsing-remitting multiple sclerosis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Dysarthria	v.24.1	
Emotional distress	v.24.1	
Gait inability	v.24.1	
Hemianaesthesia	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pyrexia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04699620	0	2021-09-22	2021-09-22	MAH	202101176661	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
70 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
MEPOLIZUMAB	Suspect		Subcutaneous	100.0 Milligram			Asthma

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bladder pain	v.24.1	
Cystitis	v.24.1	
Pleural effusion	v.24.1	
Pneumonia	v.24.1	
Weight decreased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04699634	0	2021-09-22	2021-09-22	MAH	202101176863	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
86 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACTEMRA	Suspect		Subcutaneous	162.0 Milligram	1 every 1 Weeks		Vasculitis, Giant cell arteritis
ACTEMRA	Suspect	NOT SPECIFIED	Subcutaneous	162.0 Milligram	1 every 1 Weeks	365.0 Days	Vasculitis, Giant cell arteritis
ALENDRONATE SODIUM	Concomitant						
CALCIUM LACTATE	Concomitant	Tablet					
CLOBETASOL	Concomitant	Cream					Aphthous ulcer
CLOZAPINE	Concomitant	Tablets					
COVID-19 VACCINE	Suspect		Unknown		Total		COVID-19 immunisation
GLYBURIDE	Concomitant	Tablets					
INSULIN	Concomitant	GLOBULES ORAL					
METFORMIN	Concomitant		Unknown				
PANTOPRAZOLE SODIUM	Concomitant						

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PLANTAGO OVATA	Concomitant						Diarrhoea
PREDNISONE	Concomitant	NOT SPECIFIED					
VALACYCLOVIR	Concomitant	NOT SPECIFIED					
XARELTO	Concomitant	Coated tablet					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Dizziness	v.24.1	
Nausea	v.24.1	
Pain in extremity	v.24.1	
Syncope	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04699680	0	2021-09-22	2021-09-22	MAH	202101176593	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
24 Years	Female		73 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AGALSIDASE ALFA	Suspect		Unknown	4.0 Dosage forms	2 every 1 Weeks		Fabry's disease
AMITRIPTYLINE	Concomitant		Unknown				
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
LAMOTRIGINE	Concomitant	Tablets					
OXCARBAZEPINE	Concomitant	NOT SPECIFIED	Unknown				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood pressure decreased	v.24.1	
Catheter site haemorrhage	v.24.1	
Dizziness	v.24.1	
Infusion related reaction	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pain in extremity	v.24.1	
Syncope	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04699715	0	2021-09-22	2021-09-22	MAH	202101176803	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
64 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CANNABIS SATIVA	Concomitant		Unknown				
COVID-19 VACCINE	Suspect		Unknown		Total		COVID-19 immunisation
FOLIC ACID	Concomitant	NOT SPECIFIED	Unknown				
HYDROXYCHLOROQUINE SULFATE	Concomitant		Unknown				
ORENCIA	Suspect		Intravenous (not otherwise specified)	750.0 Milligram	Cyclical		Rheumatoid arthritis
PERINDOPRIL	Concomitant		Unknown				
SYNTHROID	Concomitant	NOT SPECIFIED	Unknown				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bone disorder	v.24.1	
Bone pain	v.24.1	
Hepatic cyst	v.24.1	
Musculoskeletal chest pain	v.24.1	
Pancreatic neoplasm	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04699930	2	2021-09-22	2021-12-21	MAH	202101176596	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
50 Years	Male		74 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETAMINOPHEN	Concomitant	NOT SPECIFIED	Unknown				
ACETYLSALICYLIC ACID	Concomitant	NOT SPECIFIED					
AGALSIDASE ALFA	Suspect	Solution for infusion	Unknown	4.0 Dosage forms			Fabry's disease
AGALSIDASE ALFA	Suspect		Unknown	14.7 Milligram			Fabry's disease
AGGRENOX	Concomitant	Capsules	Unknown				
AGGRENOX	Concomitant	CAPSULE (IMMEDIATE AND EXTENDED RELEASE)	Unknown				
ALLOPURINOL	Concomitant	Tablets	Unknown				
ALLOPURINOL	Concomitant	Tablet	Unknown				
AMLODIPINE BESILATE	Concomitant			2.5 Milligram			Hypertension
CINACALCET	Concomitant	Tablet	Unknown				

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CINACALCET	Concomitant	Tablets	Unknown				
CLOPIDOGREL BISULFATE	Concomitant						
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
DIPYRIDAMOLE	Concomitant	NOT SPECIFIED	Unknown				
LEVETIRACETAM	Concomitant	Tablet	Oral	750.0 Milligram	2 every 1 Days		
LEVETIRACETAM	Concomitant	Tablets	Oral	750.0 Milligram	2 every 1 Days		
LOSARTAN POTASSIUM	Concomitant	Tablets	Unknown				
LOSARTAN POTASSIUM	Concomitant	Tablet	Unknown				
MYCOPHENOLATE MOFETIL	Concomitant	NOT SPECIFIED	Unknown				
PREDNISONE	Concomitant	NOT SPECIFIED	Unknown				
RAMIPRIL	Concomitant	NOT SPECIFIED		10.0 Milligram	1 every 1 Days		Hypertension
RANITIDINE	Concomitant		Unknown				
RENAGEL [SEVELAMER]	Concomitant		Unknown				
SIMVASTATIN	Concomitant	Tablets	Unknown				
SIMVASTATIN	Concomitant	Tablet	Unknown				
SODIUM BICARBONATE	Concomitant	NOT SPECIFIED	Unknown				
SULFAMETHOXAZOLE	Concomitant		Unknown				
TACROLIMUS	Concomitant	Capsules	Unknown				
TACROLIMUS	Concomitant	Capsules	Unknown				
TAMSULOSIN	Concomitant	NOT SPECIFIED	Unknown				
VITAMIN D3	Concomitant	Capsules	Unknown				
VITAMIN D3	Concomitant	Capsules					
XARELTO	Concomitant	Coated tablet	Unknown				
XARELTO	Concomitant	Coated tablet	Unknown				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Back pain	v.24.1	
Blood pressure increased	v.24.1	
Cerebrovascular accident	v.24.1	
Dysarthria	v.24.1	
Fall	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	
Headache	v.24.1	
Heart rate increased	v.24.1	
Hypoaesthesia	v.24.1	
Infusion related reaction	v.24.1	
Malaise	v.24.1	
Pain	v.24.1	
Pain in extremity	v.24.1	
Pelvic pain	v.24.1	
Phlebotomy	v.24.1	
Poor venous access	v.24.1	
Respiratory rate increased	v.24.1	
Vaccination site pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04702507	0	2021-09-23	2021-09-23	MAH	20210929667	Study	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular				Product used for unknown indication
IMBRUVICA	Suspect	Capsules	Oral	420.0 Milligram			Waldenstrom's macroglobulinaemia

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Antibody test abnormal	v.24.1	
Helicobacter infection	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04703783	1	2021-09-23	2021-09-27	MAH	202101182097	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
65 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
HUMIRA	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous	80.0 Milligram	1 every 1 Weeks		Crohn's disease

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Crohn's disease	v.24.1	
Drug ineffective	v.24.1	
Drug level abnormal	v.24.1	
Faecal calprotectin increased	v.24.1	
Suspected COVID-19	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04703892	2	2021-09-23	2021-12-21	MAH	202101182076	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
61 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
CUTAQUIG	Concomitant		Subcutaneous	2.0 Milligram			
HUMAN C1 ESTERASE INHIBITOR	Concomitant		Intravenous (not otherwise specified)	1500.0 ml			
IMMUNOGLOBULIN (HUMAN)	Suspect		Subcutaneous	8.0 Gram	1 every 1 Weeks		Secondary immunodeficiency

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Allergy to vaccine	v.24.1	
Anaphylactic reaction	v.24.1	14 Days
Angioedema	v.24.1	14 Days

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Medication error	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04704010	1	2021-09-23	2021-12-23	MAH	202101182113	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
48 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
OCRELIZUMAB	Suspect		Intravenous (not otherwise specified)	300.0 Milligram	Cyclical		Relapsing-remitting multiple sclerosis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Decreased appetite	v.24.1	
Dizziness	v.24.1	
Dysstasia	v.24.1	
Hypoaesthesia	v.24.1	
Hypoxia	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Loss of personal independence in daily activities	v.24.1	
Nausea	v.24.1	
Palpitations	v.24.1	
Somnolence	v.24.1	
Vertigo	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04717138	5	2021-09-28	2021-11-24	MAH	CA2021184912	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
53 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				Product used for unknown indication
HYDROMORPHONE	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication
METOCLOPRAMIDE	Concomitant		Unknown				Product used for unknown indication
PROPRANOLOL	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication
RANITIDINE	Concomitant		Unknown				Product used for unknown indication

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ZEJULA	Suspect	Capsules	Oral	200.0 Milligram	1 every 1 Days	17.0 Days	Ovarian epithelial cancer, Malignant peritoneal neoplasm, Fallopian tube cancer
ZEJULA	Suspect	Capsules	Unknown				Ovarian epithelial cancer, Malignant peritoneal neoplasm, Fallopian tube cancer
ZEJULA	Suspect	Capsules	Oral	100.0 Milligram	1 every 1 Days		Ovarian epithelial cancer, Malignant peritoneal neoplasm, Fallopian tube cancer

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Blood pressure increased	v.24.1	
Condition aggravated	v.24.1	
Constipation	v.24.1	
Dry mouth	v.24.1	
Fatigue	v.24.1	
Haematocrit decreased	v.24.1	
Haemoglobin decreased	v.24.1	
Headache	v.24.1	
Lymphocyte count increased	v.24.1	
Monocyte count increased	v.24.1	
Nausea	v.24.1	
Neutrophil count decreased	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Night sweats	v.24.1	
Platelet count decreased	v.24.1	
Red blood cell count decreased	v.24.1	
Tinnitus	v.24.1	
Vomiting	v.24.1	
White blood cell count decreased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:08:27 AM
Initial Received Date: 2021-07-30 to 2021-09-30
Latest Received Date: N/A
Total Number of Reports: 703 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04718385	1	2021-09-28	2021-11-17	MAH	202101211238	Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
46 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown		Total		COVID-19 immunisation
XELJANZ XR	Concomitant	TABLET (EXTENDED-RELEASE)					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.24.1	
Vaccination failure	v.24.1	

Health Canada Santé Canada

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:09:42 AM
Initial Received Date:	2021-09-30 to 2021-12-30
Latest Received Date:	N/A
Total Number of Reports:	197 Report(s)

Brand Name/Active Ingredient: covid
Search Date Criteria: 2021-09-30 to 2021-12-30
Reaction Term(s): All/Tous
Serious report?: Both
Type of Report: All
Source of Report: All
Gender: All
Report Outcome: All
Age: All

CAVEAT: This summary is based on information from adverse reaction reports submitted by health professionals and laypersons either directly to Health Canada or via market authorization holders. Each report represents the suspicion, opinion or observation of the individual reporter. The Canada Vigilance Program is a spontaneous reporting system that is suitable to detect signals of potential health product safety issues during the post-market period. The data has been collected primarily by a spontaneous surveillance system in which adverse reactions to health products are reported on a voluntary basis. Under reporting of adverse reactions is seen with both voluntary and mandatory spontaneous surveillance systems. Accumulated case reports should not be used as a basis for determining the incidence of a reaction or estimating risk for a particular product as neither the total number of reactions occurring, nor the number of patients exposed to the health product is known. Because of the multiple factors that influence reporting, quantitative comparisons of health product safety cannot be made from the data. Some of these factors include the length of time a drug is marketed, the market share, size and sophistication of the sales force, publicity about an adverse reaction and regulatory actions. In some cases, the reported clinical data is incomplete and there is not certainty that these health products caused the reported reactions. A given reaction may be due to an underlying disease process or to another coincidental factor. This information is provided with the understanding that the data will be appropriately referenced and used in conjunction with this caveat statement.

Canada

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000971623	0	2021-10-15	2021-10-15	Community		Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
46 Years	Female	169 Centimeter	149 Pound	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR			Once		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	
Hypoaesthesia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000973210	0	2021-10-26	2021-10-26	Community		Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
62 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	000973091

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					
COVID-19 VACCINE	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Nausea	v.24.1	
Vertigo	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000973216	0	2021-10-26	2021-10-26	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
62 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	000973078
Linked	000945493

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Erythema	v.24.1	
Rash	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:09:42 AM
Initial Received Date:	2021-09-30 to 2021-12-30
Latest Received Date:	N/A
Total Number of Reports:	197 Report(s)

Report Information

***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000973677	0	2021-10-29	2021-10-29	Community		Spontaneous	Pharmacist

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
73 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AIMOVIG PREFILLED AUTO-INJECTOR	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous	140.0 Milligram	1 every 1 Months		Migraine
COVID-19 VACCINE	Suspect						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Herpes zoster	v.24.1	13 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000973941	0	2021-11-01	2021-11-01	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
25 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	000973959

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID VACCINE	Suspect						
COVID VACCINE	Suspect						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Menstruation delayed	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000973959	0	2021-11-01	2021-11-01	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
25 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	000973941

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID VACCINE	Suspect						
COVID VACCINE	Suspect						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Amenorrhoea	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000974670	0	2021-11-05	2021-11-05	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Salivary gland enlargement	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000974901	0	2021-11-08	2021-11-08	Community		Spontaneous	Other health professional

Serious report?	Death:	Yes	Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Fatal

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Confusional state	v.24.1	
Decreased appetite	v.24.1	
Lethargy	v.24.1	
Mobility decreased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000975952	0	2021-11-16	2021-11-16	Hospital		Spontaneous	Other health professional

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:	Yes	Other Medically Important Conditions:	

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Recovering/resolving

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BENADRYL	Concomitant	NOT SPECIFIED					
COVID-19 VACCINE	Suspect						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.24.1	
Dysphonia	v.24.1	
Hyperhidrosis	v.24.1	
Tachycardia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000976464	0	2021-11-19	2021-11-19	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:		Disability:		Congenital Anomaly:	
Not Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID VACCINE	Suspect				Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Oral herpes	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000976673	0	2021-11-22	2021-11-22	Hospital		Spontaneous	Other health professional

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:	Yes	Other Medically Important Conditions:	

Patient Information

Age	Gender	Height	Weight	Report Outcome
29 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect						COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Myocarditis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000977404	0	2021-10-21	2021-10-21	Hospital		Spontaneous	Other health professional

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
96 Years	Female		58 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Clostridium difficile infection	v.24.1	
Injection site cellulitis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000977561	0	2021-11-04	2021-11-04	Community		Spontaneous	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
45 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	000974640

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID VACCINE	Suspect						
OCREVUS SINGLE-USE VIAL	Concomitant	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	600.0 Milligram	1 every 6 Months		Multiple sclerosis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bedridden	v.24.1	
Fatigue	v.24.1	
Multiple sclerosis relapse	v.24.1	
Pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000977755	0	2021-11-24	2021-11-24	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
38 Years	Female	157 Centimeter	170 Pound	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect	Injection					COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Injection site pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000977796	0	2021-11-29	2021-11-29	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:	Disability:	Congenital Anomaly:
Not Serious	Life Threatening:	Hospitalization:	Other Medically Important Conditions:

Patient Information

Age	Gender	Height	Weight	Report Outcome
34 Years	Female			Recovering/resolving

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PFIZER-BIONTECH COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.3 ML	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Menstrual disorder	v.24.1	
Oligomenorrhoea	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000978332	0	2021-12-01	2021-12-01	MAH		Study	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
48 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	000965511

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect						Product used for unknown indication
COVID-19 VACCINE	Suspect		Unknown				Product used for unknown indication
HYDROXYCHLOROQUINE	Concomitant	Tablets					
IDACIO	Suspect	Solution	Subcutaneous	40.0 Milligram	1 every 2 Weeks		Rheumatoid arthritis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthritis	v.24.1	
Drug ineffective	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Feeling hot	v.24.1	
Pain in extremity	v.24.1	
Peripheral swelling	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000979664	0	2021-12-08	2021-12-08	Community		Spontaneous	Pharmacist

Serious report?	Death:		Disability:		Congenital Anomaly:	
Not Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	

Patient Information

Age	Gender	Height	Weight	Report Outcome
61 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	000979894

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AUBAGIO	Suspect	Tablets	Oral	14.0 Milligram	1 every 1 Days		Multiple sclerosis
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Paralysis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000979894	0	2021-12-08	2021-12-08	Community		Spontaneous	Pharmacist

Serious report?	Death:		Disability:		Congenital Anomaly:	
Not Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	

Patient Information

Age	Gender	Height	Weight	Report Outcome
61 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	000979664

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AUBAGIO	Suspect	Tablets	Oral	14.0 Milligram	1 every 1 Days		Multiple sclerosis
MODERNA COVID-19 VACCINE VIAL CONTAINS 10 DOSES OF 0.5ML	Suspect						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Paralysis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000980318	0	2021-12-14	2021-12-14	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:		Disability:		Congenital Anomaly:	
Serious	Life Threatening:		Hospitalization:	Yes	Other Medically Important Conditions:	

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Impaired work ability	v.24.1	
Myocarditis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000980906	0	2021-12-17	2021-12-17	Community		Spontaneous	Consumer/other non health professional

Serious report?	Death:		Disability:		Congenital Anomaly:	
Not Serious	Life Threatening:		Hospitalization:		Other Medically Important Conditions:	

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
JANSSEN COVID-19 VACCINE VIAL CONTAINS 5 DOSES OF 0.5ML	Suspect	SUSPENSION INTRAMUSCULAR					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain upper	v.24.1	
Chills	v.24.1	
Disorientation	v.24.1	
Headache	v.24.1	
Hyperhidrosis	v.24.1	
Myalgia	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Nausea	v.24.1	
Pyrexia	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04739558	2	2021-10-04	2021-12-22	MAH	BL-2021-019744	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
55 Years	Female	152 Centimeter	134 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CITALOPRAM	Concomitant		Oral	40.0 Milligram	1 every 1 Days		Anxiety
CITALOPRAM	Concomitant		Oral	40.0 Milligram	1 every 1 Days		Anxiety
CITALOPRAM	Concomitant		Oral	20.0 Milligram	1 every 1 Days	126.0 Days	Anxiety
CONTRAVE	Suspect	Tablet	Oral		1 every 12 Hours		Weight control
CONTRAVE	Suspect	Tablet	Oral		1 every 12 Hours		Weight control
CONTRAVE	Suspect	Tablet	Oral	2.0 Dosage forms	1 every 12 Hours	190.0 Days	Weight control
CONTRAVE	Suspect	TABLET (EXTENDED-RELEASE)	Oral	1.0 Dosage forms	1 every 1 Days	7.0 Days	Weight control
CONTRAVE	Suspect	Tablet	Oral	1.0 Dosage forms	1 every 12 Hours	7.0 Days	Weight control
COVID-19 VACCINE	Suspect		Intramuscular		1 every 1 Days	1.0 Days	COVID-19 immunisation

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
VITAMIN D	Concomitant	NOT SPECIFIED	Oral	2000.0 IU (International Unit)	1 every 1 Days		Vitamin supplementation
VITAMIN D	Concomitant		Oral	20.0 Milligram	1 every 1 Days	126.0 Days	Vitamin supplementation
VITAMIN D	Concomitant		Oral	40.0 Milligram	1 every 1 Days		Vitamin supplementation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abnormal dreams	v.24.1	1 Months
Chills	v.24.1	4 Days
Constipation	v.24.1	-148
Dehydration	v.24.1	4 Days
Depression suicidal	v.24.1	15 Days
Dry mouth	v.24.1	
Headache	v.24.1	4 Days
Hot flush	v.24.1	
Hyperhidrosis	v.24.1	
Insomnia	v.24.1	
Nausea	v.24.1	4 Days
Pyrexia	v.24.1	4 Days
Sleep apnoea syndrome	v.24.1	
Sleep terror	v.24.1	
Vomiting	v.24.1	4 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04742363	0	2021-10-05	2021-10-05	MAH	20210538506	Study	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
49 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				COVID-19 prophylaxis
REMICADE	Suspect	POWDER FOR SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)				Crohn's disease

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pulmonary sarcoidosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:09:42 AM
Initial Received Date:	2021-09-30 to 2021-12-30
Latest Received Date:	N/A
Total Number of Reports:	197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04742734	1	2021-10-05	2021-10-26	MAH	2924985	Study	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
67 Years	Female		68 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACTEMRA	Suspect	NOT SPECIFIED	Subcutaneous	162.0 Milligram	1 every 2 Weeks		Rheumatoid arthritis
COVID-19 VACCINE	Suspect		Unknown				Product used for unknown indication
FOLIC ACID	Concomitant	NOT SPECIFIED					
METHOTREXATE	Concomitant	NOT SPECIFIED	Intrathecal				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Osteoarthritis	v.24.1	
Therapeutic product effect decreased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04745893	0	2021-10-06	2021-10-06	MAH	21K-028-3831410-00	Study	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
74 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular			0.0	COVID-19 immunisation
COVID-19 VACCINE	Suspect		Intramuscular			1.0 Days	COVID-19 immunisation
RISANKIZUMAB	Suspect		Subcutaneous	150.0 Milligram	1 every 12 Weeks	-48.0	Psoriasis
RISANKIZUMAB	Suspect	Solution for injection in pre-filled syringe	Subcutaneous	150.0 Milligram	1 every 6 Weeks		Psoriasis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Condition aggravated	v.24.1	
Drug ineffective	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Injection site pain	v.24.1	1 Days
Psoriasis	v.24.1	
Therapeutic response shortened	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04749605	0	2021-10-07	2021-10-07	MAH	21K-028-4105723-00	Study	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
47 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular			0.0	COVID-19 immunisation
HUMIRA	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous	40.0 Milligram	1 every 2 Weeks		Psoriatic arthropathy, Psoriasis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Drug ineffective	v.24.1	
Psoriatic arthropathy	v.24.1	0

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04751076	0	2021-10-07	2021-10-07	MAH	21K-028-4099031-00	Study	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
31 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular			0.0	COVID-19 prophylaxis
COVID-19 VACCINE	Suspect	Injection	Intramuscular			0.0	COVID-19 prophylaxis
HUMIRA	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous	40.0 Milligram	1 every 1 Weeks	547.0	Hidradenitis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hidradenitis	v.24.1	
Pain	v.24.1	
Therapeutic product effect decreased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04753198	0	2021-10-07	2021-10-07	MAH	21K-028-4099484-00	Study	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
39 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular			0.0	COVID-19 immunisation
HUMIRA	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous	40.0 Milligram	1 every 2 Weeks		Crohn's disease

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Crohn's disease	v.24.1	
Drug ineffective	v.24.1	
Hospitalisation	v.24.1	
Injection site pain	v.24.1	
Intestinal resection	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:09:42 AM
Initial Received Date:	2021-09-30 to 2021-12-30
Latest Received Date:	N/A
Total Number of Reports:	197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04761665	1	2021-10-11	2021-10-18	MAH	2020TUS056792	Study	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
76 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				Product used for unknown indication
IMMUNOGLOBULIN (HUMAN)	Suspect	Solution for infusion	Unknown	60.0 ml	1 every 1 Weeks		Secondary immunodeficiency
IMMUNOGLOBULIN (HUMAN)	Suspect		Unknown	12.0 Gram	1 every 1 Weeks		Secondary immunodeficiency
IMMUNOGLOBULIN (HUMAN)	Suspect	Solution for infusion	Unknown	12.0 Gram	1 every 1 Weeks		Secondary immunodeficiency

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.24.1	
Cardiac disorder	v.24.1	
Renal disorder	v.24.1	
Vaccination failure	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:09:42 AM
Initial Received Date:	2021-09-30 to 2021-12-30
Latest Received Date:	N/A
Total Number of Reports:	197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04762423	0	2021-10-11	2021-10-11	MAH	CA202012460	Study	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
47 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BERINERT	Concomitant		Unknown				Product used for unknown indication
COVID-19 VACCINE	Suspect		Unknown				Product used for unknown indication
ICATBANT ACETATE	Suspect	Solution for injection in pre-filled syringe	Unknown				Hereditary angioedema
ICATBANT ACETATE	Suspect		Unknown	30.0 Milligram			Hereditary angioedema
ICATBANT ACETATE	Suspect	Solution for injection in pre-filled syringe	Unknown	30.0 Milligram			Hereditary angioedema
ICATBANT ACETATE	Suspect	Solution for injection in pre-filled syringe	Unknown	30.0 Milligram			Hereditary angioedema

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ICATBANT ACETATE	Suspect	Solution for injection in pre-filled syringe	Unknown				Hereditary angioedema
ICATBANT ACETATE	Suspect	Solution for injection in pre-filled syringe	Unknown	30.0 Milligram			Hereditary angioedema
LITHIUM	Concomitant		Unknown				Product used for unknown indication
MYRBETRIQ	Concomitant	TABLET (EXTENDED-RELEASE)	Unknown				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal discomfort	v.24.1	
Abdominal pain	v.24.1	
Haematochezia	v.24.1	
Ingrowing nail	v.24.1	
Muscle spasms	v.24.1	
Peripheral swelling	v.24.1	
Polyp	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04763945	1	2021-10-12	2021-10-19	MAH	CA2021AMR105597	Study	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_03643379
Linked	E2B_03643379

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				COVID-19 prophylaxis
MEPOLIZUMAB	Suspect	Powder for injection	Subcutaneous	100.0 Milligram			Asthma
MEPOLIZUMAB	Suspect		Subcutaneous	100.0 Milligram			Asthma
MEPOLIZUMAB	Suspect	Solution for injection in pre-filled pen	Subcutaneous	100.0 Milligram			Asthma

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthroscopy	v.24.1	
Knee operation	v.24.1	
Mobility decreased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04768415	0	2021-10-12	2021-10-12	MAH	2020-09420	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
71 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COLACE	Concomitant	NOT SPECIFIED			every 1 Days		
COVID-19 VACCINE	Suspect		Unknown				COVID-19 immunisation
DESOXIMETASONE	Concomitant	NOT SPECIFIED					

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
DEXILANT	Concomitant	CAPSULE, DELAYED RELEASE			every 1 Days		
LAX-A-DAY	Concomitant	POWDER FOR SOLUTION ORAL			every 1 Days		
SENOKOT	Concomitant	Tablet			every 1 Days		
SOMATULINE AUTOGEL PRE-FILLED SYRINGE	Suspect	SOLUTION (EXTENDED RELEASE)	Subcutaneous	120.0 Milligram	every 28 Days		Neuroendocrine tumour
TEVA-DULOXETINE	Concomitant	NOT SPECIFIED			every 2 Days		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal discomfort	v.24.1	
Abdominal tenderness	v.24.1	
Arthralgia	v.24.1	
Asthenia	v.24.1	
Back pain	v.24.1	
Breast mass	v.24.1	
Chest pain	v.24.1	20 Days
Constipation	v.24.1	
Discomfort	v.24.1	
Dizziness	v.24.1	
Fall	v.24.1	
Fall	v.24.1	1 Days
Fatigue	v.24.1	
Muscular weakness	v.24.1	
Myalgia	v.24.1	
Neoplasm progression	v.24.1	
Osteoarthritis	v.24.1	
Pain in extremity	v.24.1	1 Days
Pallor	v.24.1	
Spinal fracture	v.24.1	
Spondylitis	v.24.1	
Tendon pain	v.24.1	
Urinary incontinence	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Vitamin D decreased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04768605	0	2021-10-12	2021-10-12	MAH	2019SA228935	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
61 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AMLODIPINE	Concomitant	Tablets	Unknown				Hypertension
AMLODIPINE BESILATE	Concomitant		Oral	2.5 Milligram	1 every 1 Days		Hypertension
AUBAGIO	Suspect	Tablets	Oral	14.0 Milligram	1 every 1 Days		Relapsing-remitting multiple sclerosis
COVID-19 VACCINE	Suspect		Unknown				COVID-19 immunisation
PERINDOPRIL	Concomitant		Unknown				
VITAMIN D	Concomitant	NOT SPECIFIED	Unknown				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Condition aggravated	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	
Gait disturbance	v.24.1	
Limb discomfort	v.24.1	
Mobility decreased	v.24.1	
Multiple sclerosis relapse	v.24.1	
Paralysis	v.24.1	
Therapeutic response decreased	v.24.1	

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Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04773942	0	2021-10-14	2021-10-14	MAH	CA2021AMR211329	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
58 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_02870550
Linked	
Linked	
Linked	E2B_03584438
Linked	
Linked	
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				Product used for unknown indication, COVID-19 prophylaxis

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				Product used for unknown indication, COVID-19 prophylaxis
COVID-19 VACCINE	Suspect		Unknown				Product used for unknown indication, COVID-19 prophylaxis
MEPOLIZUMAB	Suspect		Subcutaneous	100.0 Milligram			Asthma
TYLENOL ARTHRITIS PAIN 8H	Suspect	TABLET (EXTENDED-RELEASE)	Unknown	1.0 Dosage forms			Pain

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	
Immunodeficiency	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Pain	v.24.1	
Product dose omission issue	v.24.1	
Scab	v.24.1	
Skin disorder	v.24.1	

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E2B_04774061	2	2021-10-14	2021-12-10	MAH	2021-22202	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
81 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown			1.0 Days	COVID-19
LISINOPRIL	Concomitant	Tablets		10.0 Milligram	every 1 Days		
PREMARIN	Concomitant	NOT SPECIFIED					
ROSUVASTATIN	Concomitant	NOT SPECIFIED		10.0 Milligram	every 1 Days		
SENOKOT	Concomitant	Tablet					
SOMATULINE AUTOGEL PRE-FILLED SYRINGE	Suspect	SOLUTION (EXTENDED RELEASE)	Subcutaneous	120.0 Milligram	every 4 Weeks		Neuroendocrine tumour
TYLENOL	Concomitant	NOT SPECIFIED					
VITAMIN B 12	Concomitant	Capsule					Vitamin B12 decreased

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal distension	v.24.1	
Abdominal pain	v.24.1	4 Days
Abdominal pain	v.24.1	5 Days
Constipation	v.24.1	
Muscle spasms	v.24.1	
Nausea	v.24.1	3 Days
Vitamin B12 decreased	v.24.1	
Vomiting	v.24.1	1 Days

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Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04774155	0	2021-10-14	2021-10-14	MAH	20210821105	Study	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
14 Years	Male	185 Centimeter	85 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	
Linked	
Linked	
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				COVID-19 prophylaxis
REMICADE	Suspect	POWDER FOR SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	900.0 Milligram	1 every 4 Weeks		Colitis ulcerative

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Diarrhoea	v.24.1	
Haematochezia	v.24.1	

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Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04785592	0	2021-10-19	2021-10-19	MAH	21K-028-4120452-00	Study	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
58 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular			0.0	COVID-19 immunisation
COVID-19 VACCINE	Suspect		Intramuscular			0.0	COVID-19 immunisation
HUMIRA	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous	40.0 Milligram	1 every 7 Days		Crohn's disease

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Adverse drug reaction	v.24.1	
Pouchitis	v.24.1	
Pulmonary thrombosis	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Thrombosis	v.24.1	

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Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04785598	2	2021-10-19	2021-11-22	MAH	21K-028-4121713-00	Study	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular			0.0	COVID-19 immunisation
COVID-19 VACCINE	Suspect		Intramuscular			0.0	COVID-19 immunisation
HUMIRA	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous	40.0 Milligram	1 every 14 Days	3.0 Years	Ankylosing spondylitis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bronchial disorder	v.24.1	
Drug ineffective	v.24.1	
Epidural injection	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hernia	v.24.1	
Inflammation	v.24.1	
Neuritis	v.24.1	
Pain	v.24.1	
Sciatica	v.24.1	

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E2B_04786962	0	2021-10-19	2021-10-19	MAH	2930575	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
31 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				Product used for unknown indication
OCRELIZUMAB	Suspect		Intravenous (not otherwise specified)	300.0 Milligram			Relapsing-remitting multiple sclerosis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal distension	v.24.1	
Abdominal pain	v.24.1	
Fatigue	v.24.1	1 Days
Gallbladder disorder	v.24.1	
Pain	v.24.1	1 Days

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Report Information ***AER = Adverse Reaction Report*

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E2B_04787155	1	2021-10-19	2021-11-15	MAH	2600708	Study	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
55 Years	Male		95 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETAMINOPHEN	Concomitant		Oral	650.0 Milligram			Premedication
ALENDRONATE SODIUM	Concomitant						
BENADRYL	Concomitant	NOT SPECIFIED	Oral	50.0 Milligram			Premedication
CALCIUM CARBONATE	Concomitant	NOT SPECIFIED					
COVID-19 VACCINE	Suspect		Unknown				Product used for unknown indication
DILTIAZEM	Concomitant						
METHYLPREDNISOLONE SODIUM SUCCINATE	Concomitant		Intravenous (not otherwise specified)	100.0 Milligram			Premedication
PANTOPRAZOLE	Concomitant	NOT SPECIFIED					
PREDNISONE	Concomitant	NOT SPECIFIED	Unknown	20.0 Milligram			

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
RITUXIMAB	Suspect	Solution for infusion	Intravenous (not otherwise specified)	1000.0 ml			Nephrotic syndrome
RITUXIMAB	Suspect		Intravenous (not otherwise specified)	1000.0 Milligram		17.0 Days	Nephrotic syndrome
RITUXIMAB	Suspect	Solution for infusion	Intravenous (not otherwise specified)	750.0 Milligram		1.0 Days	Nephrotic syndrome
ROSUVASTATIN CALCIUM	Concomitant						
SULFATRIM [SULFAMETHOXAZOLE;TRIMETHOPRIM]	Concomitant						
TACROLIMUS	Concomitant	Capsules					
ZOPICLONE	Concomitant	Tablets	Unknown	7.5 Milligram			Sleep disorder

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood pressure diastolic abnormal	v.24.1	
Blood pressure diastolic increased	v.24.1	
Fluid retention	v.24.1	
Off label use	v.24.1	
Reaction to preservatives	v.24.1	
Renal impairment	v.24.1	
Unevaluable event	v.24.1	

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E2B_04795026	0	2021-10-20	2021-10-20	MAH	CA202110005185	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
37 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ADCIRCA	Suspect	Tablets	Unknown				Pulmonary arterial hypertension
COVID-19 VACCINE	Suspect		Unknown				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal discomfort	v.24.1	
Amnesia	v.24.1	
Dizziness	v.24.1	
Feeling abnormal	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Loss of consciousness	v.24.1	

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E2B_04798528	0	2021-10-21	2021-10-21	MAH	202101367073	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
50 Years	Female		57 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BETAMETHASONE	Concomitant		Unknown				
CANNABIDIOL	Concomitant		Unknown				
CELEBREX	Concomitant	Capsules	Unknown	200.0 Milligram			
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
HIZENTRA ALSO KNOW AS IMMUNE GLOBULIN (HUMAN). SINGLE USE VIALS	Concomitant	SOLUTION SUBCUTANEOUS	Unknown			1460.0 Days	
HIZENTRA ALSO KNOW AS IMMUNE GLOBULIN (HUMAN). SINGLE USE VIALS	Concomitant		Unknown			1825.0 Days	
HYDROXYCHLOROQUINE SULFATE	Concomitant		Unknown	200.0 Milligram			

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
IMMUNOGLOBULIN (HUMAN)	Suspect		Unknown	1.0 Gram			Primary immunodeficiency syndrome
IMMUNOGLOBULIN (HUMAN)	Suspect		Subcutaneous	16.0 Gram	1 every 1 Weeks		Primary immunodeficiency syndrome
TECTA	Concomitant	NOT SPECIFIED	Unknown				
TRAMACET [TRAMADOL HYDROCHLORIDE]	Concomitant		Unknown				
VENTOLINE [SALBUTAMOL]	Concomitant		Unknown				
VIDEXTRA	Concomitant	Tablets	Unknown	10000.0 IU (International Unit)			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest discomfort	v.24.1	
Drug interaction	v.24.1	
Headache	v.24.1	
Hypersensitivity	v.24.1	
Lip pruritus	v.24.1	
Lip swelling	v.24.1	
Migraine	v.24.1	
Paraesthesia oral	v.24.1	
Rash	v.24.1	
Swollen tongue	v.24.1	
Tongue pruritus	v.24.1	
Vaccination site erythema	v.24.1	
Vaccination site pruritus	v.24.1	

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E2B_04801281	1	2021-10-22	2021-11-10	MAH	21K-028-4125604-00	Study	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
78 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular			0.0	COVID-19 prophylaxis
COVID-19 VACCINE	Suspect		Intramuscular			0.0	COVID-19 prophylaxis
HUMIRA	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous	40.0 Milligram	1 every 14 Days		Rheumatoid arthritis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Back pain	v.24.1	
Hyperaesthesia	v.24.1	
Localised oedema	v.24.1	
Malaise	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Spinal fusion surgery	v.24.1	
Therapeutic product effect decreased	v.24.1	

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E2B_04808812	3	2021-10-25	2021-12-06	MAH	BL-2021-032848	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
41 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				Product used for unknown indication
COVID-19 VACCINE	Suspect		Unknown				Product used for unknown indication
METFORMIN	Concomitant		Unknown				Product used for unknown indication
SILIQ 2 SINGLE USE PREFILLED SYRINGES	Suspect	Solution for injection	Subcutaneous	210.0 Milligram	1 every 2 Weeks		Psoriasis
SILIQ 2 SINGLE USE PREFILLED SYRINGES	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous	210.0 Milligram	1 every 1 Weeks	16.0 Days	Psoriasis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal hernia	v.24.1	
Constipation	v.24.1	
Decreased appetite	v.24.1	
Dizziness postural	v.24.1	
Heart rate increased	v.24.1	
Intentional dose omission	v.24.1	
Pyrexia	v.24.1	

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E2B_04810100	0	2021-10-25	2021-10-25	MAH	2021SA025312	Study	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
44 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AUBAGIO	Suspect	Tablets	Oral	14.0 Milligram	1 every 1 Days	283.0 Days	Relapsing-remitting multiple sclerosis
CANAGLIFLOZIN	Concomitant		Unknown	50.0 Milligram			
COVID-19 VACCINE	Suspect		Unknown				COVID-19 immunisation
INS.	Concomitant	GLOBULES ORAL	Unknown				
ROSUVASTATIN CALCIUM	Concomitant		Unknown	10.0 Milligram			
VITAMIN D	Concomitant		Unknown				
ZOPICLONE	Concomitant	Tablets	Unknown		1 every 1 Days		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain upper	v.24.1	
Constipation	v.24.1	
Decreased appetite	v.24.1	
Drug ineffective	v.24.1	
Hyperglycaemia	v.24.1	
Insomnia	v.24.1	
Multiple sclerosis	v.24.1	
Multiple sclerosis relapse	v.24.1	
Nausea	v.24.1	
Palpitations	v.24.1	
Unevaluable event	v.24.1	
Visual field defect	v.24.1	

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Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04814761	1	2021-10-26	2021-12-20	MAH	202101359302	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
42 Years	Male		103 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AZATHIOPRINE	Concomitant	NOT SPECIFIED	Oral	150.0 Milligram	1 every 1 Days		Colitis ulcerative
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
REMICADE	Suspect	Powder for solution for infusion	Intravenous (not otherwise specified)	500.0 Milligram			Colitis ulcerative
REMICADE	Suspect	Solution for infusion	Intravenous (not otherwise specified)	5.0 mg/kg			Colitis ulcerative
REMICADE	Suspect	POWDER FOR SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	5.0 mg/kg			Colitis ulcerative

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal discomfort	v.24.1	3 Months
Bone pain	v.24.1	
Defaecation urgency	v.24.1	
Diarrhoea	v.24.1	
Frequent bowel movements	v.24.1	
Haematochezia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04814762	0	2021-10-26	2021-10-26	MAH	202101359495	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
64 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
HUMIRA	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous	40.0 Milligram			Colitis ulcerative

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cardiac disorder	v.24.1	
Herpes zoster	v.24.1	
Nephrolithiasis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:09:42 AM
Initial Received Date:	2021-09-30 to 2021-12-30
Latest Received Date:	N/A
Total Number of Reports:	197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04814769	0	2021-10-26	2021-10-26	MAH	202101359422	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
34 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AVONEX	Suspect	POWDER FOR SOLUTION INTRAMUSCULAR	Intramuscular	30.0 Microgram	1 every 1 Weeks		Multiple sclerosis
COVID-19 VACCINE	Suspect		Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Multiple sclerosis relapse	v.24.1	
Vaccination complication	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04814774	0	2021-10-26	2021-10-26	MAH	202101359289	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACTEMRA	Suspect	NOT SPECIFIED	Subcutaneous	163.0 Milligram			Rheumatoid arthritis
BISOPROLOL	Concomitant		Unknown				
CALCIUM;MAGNESIUM	Concomitant						
COVID-19 VACCINE	Suspect		Unknown		Total		COVID-19 immunisation
ESCITALOPRAM	Concomitant	Tablets					
FOLIC ACID	Concomitant	NOT SPECIFIED					
JARDIANCE	Concomitant						
LEFLUNOMIDE	Concomitant	NOT SPECIFIED					
LEUCOVORIN [FOLINIC ACID]	Concomitant		Unknown		1 every 1 Weeks		
LEVOTHYROXINE SODIUM	Concomitant	NOT SPECIFIED	Unknown				
MAGNESIUM	Concomitant	NOT SPECIFIED					

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
METFORMIN HYDROCHLORIDE/SITAGLIPTIN PHOSPHATE MONOHYDRATE	Concomitant						
METHOTREXATE	Concomitant	NOT SPECIFIED	Intrathecal				
PREDNISONE	Concomitant	NOT SPECIFIED					
PREGABALIN	Concomitant	Capsules					
RABEPRAZOLE	Concomitant						
RAMIPRIL	Concomitant	NOT SPECIFIED					
RISEDRONATE	Concomitant	Tablets	Unknown		1 every 1 Months		
ROSUVASTATIN	Concomitant	NOT SPECIFIED	Subcutaneous				
VITAMIN D3	Concomitant	Capsules					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	
Gait inability	v.24.1	
Headache	v.24.1	
Hypotension	v.24.1	
Pyrexia	v.24.1	
Thrombosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04815394	4	2021-10-26	2021-12-28	MAH	2021SA033026	Study	Other health professional

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
73 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CALCIUM	Concomitant	NOT SPECIFIED	Unknown				
COVID-19 VACCINE	Suspect		Unknown				COVID-19 immunisation
COVID-19 VACCINE	Suspect		Unknown				COVID-19 immunisation
COVID-19 VACCINE	Suspect		Unknown				COVID-19 immunisation
FOLIC ACID	Concomitant		Unknown				
FOLIC ACID	Concomitant	NOT SPECIFIED	Unknown				
GLUCOSAMINE	Concomitant	NOT SPECIFIED	Unknown				
KEVZARA	Suspect	Solution for injection	Unknown				Rheumatoid arthritis
KEVZARA	Suspect		Subcutaneous	200.0 Milligram	1 every 2 Weeks	8.0 Months	Rheumatoid arthritis

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
METHOTREXATE	Concomitant	NOT SPECIFIED	Unknown				
VITAMIN D	Concomitant	NOT SPECIFIED	Unknown				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Amnesia	v.24.1	
Arthralgia	v.24.1	
Arthralgia	v.24.1	
Blood pressure abnormal	v.24.1	
Cataract	v.24.1	
Condition aggravated	v.24.1	
Cough	v.24.1	
Dyspnoea	v.24.1	
Heart rate increased	v.24.1	
Heart rate irregular	v.24.1	
Impaired driving ability	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Inflammation	v.24.1	
Intentional dose omission	v.24.1	
Joint range of motion decreased	v.24.1	
Joint swelling	v.24.1	
Laboratory test abnormal	v.24.1	
Muscle atrophy	v.24.1	
Nasal congestion	v.24.1	
Neck pain	v.24.1	
Osteoporosis	v.24.1	
Pain	v.24.1	
Pneumothorax	v.24.1	
Pneumothorax	v.24.1	
Pollakiuria	v.24.1	
Product storage error	v.24.1	
Product temperature excursion issue	v.24.1	
Pulmonary oedema	v.24.1	
Rheumatoid arthritis	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Supraventricular extrasystoles	v.24.1	
Therapeutic response decreased	v.24.1	
Therapeutic response unexpected	v.24.1	
Thoracic cavity drainage	v.24.1	
Unevaluable event	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04819807	0	2021-10-27	2021-10-27	MAH	202101367316	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
56 Years	Female		75 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
REMICADE	Suspect	POWDER FOR SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	600.0 Milligram	Cyclical		Rheumatoid arthritis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bronchitis	v.24.1	2 Months
Off label use	v.24.1	
Pneumonia	v.24.1	2 Months
Product use issue	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04819820	0	2021-10-27	2021-10-27	MAH	202101367352	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
61 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
RINVOQ	Suspect	TABLET (EXTENDED-RELEASE)	Oral	15.0 Milligram	1 every 1 Days	61.0 Days	Rheumatoid arthritis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Drug ineffective	v.24.1	
Nausea	v.24.1	
Suspected COVID-19	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04819832	2	2021-10-27	2021-12-21	MAH	202101367196	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
38 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ADVAIR	Concomitant	NOT SPECIFIED	Unknown				
ALVESCO	Concomitant	AEROSOL, METERED DOSE	Unknown				
ATROVENT	Concomitant	NOT SPECIFIED	Unknown				
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
DILAUDID	Concomitant	NOT SPECIFIED	Unknown				
HYDROMORPH CONTIN	Concomitant	CAPSULE, SUSTAINED-RELEASE	Unknown				
IRON	Concomitant		Unknown				
LYRICA	Concomitant	Capsules	Unknown				
MAGNESIUM ASPARTATE	Concomitant		Unknown				
MEPOLIZUMAB	Suspect	Powder for injection	Subcutaneous	100.0 Milligram			Asthma

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MEPOLIZUMAB	Suspect		Subcutaneous	100.0 Milligram			Asthma
MONTELUKAST SODIUM	Concomitant		Unknown				
OMALIZUMAB	Suspect		Unknown				Product used for unknown indication
PANTOPRAZOLE SODIUM	Concomitant		Unknown				
PREDNISONE	Concomitant	NOT SPECIFIED	Unknown				
PREGABALIN	Concomitant	Capsules	Unknown				
PROZAC	Concomitant	NOT SPECIFIED	Unknown				
TRAZODONE	Concomitant		Unknown				
VENTOLIN [SALBUTAMOL]	Concomitant		Unknown				
VITAMIN D	Concomitant	NOT SPECIFIED	Unknown				
XARELTO	Concomitant	Coated tablet	Unknown				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Carpal tunnel syndrome	v.24.1	
Chills	v.24.1	3 Days
Fatigue	v.24.1	
Headache	v.24.1	
Heart rate increased	v.24.1	
Impaired gastric emptying	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Influenza like illness	v.24.1	
Product dose omission issue	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04819833	0	2021-10-27	2021-10-27	MAH	202101367034	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
83 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Duplicate	E2B_04569740

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ATORVASTATIN CALCIUM	Concomitant	NOT SPECIFIED	Unknown				
BACLOFEN	Concomitant	NOT SPECIFIED	Unknown				
BRODALUMAB	Suspect		Subcutaneous	210.0 Milligram			Psoriasis
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
FUROSEMIDE	Concomitant	NOT SPECIFIED	Unknown				
INDAPAMIDE;PERINDOPRIL ERBUMINE	Concomitant		Unknown				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthritis	v.24.1	
Fatigue	v.24.1	
Headache	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Infection	v.24.1	
Limb mass	v.24.1	
Muscular weakness	v.24.1	
Pain	v.24.1	
Peripheral swelling	v.24.1	
Pruritus	v.24.1	
Psoriasis	v.24.1	
Psoriatic arthropathy	v.24.1	
Somnolence	v.24.1	
Thyroid function test abnormal	v.24.1	
Vaccination site discharge	v.24.1	
Vaccination site haemorrhage	v.24.1	
Vaccination site vesicles	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:09:42 AM
Initial Received Date:	2021-09-30 to 2021-12-30
Latest Received Date:	N/A
Total Number of Reports:	197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04819838	0	2021-10-27	2021-10-27	MAH	202101367227	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
56 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
HUMIRA	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous	40.0 Milligram		3650.0 Days	Rheumatoid arthritis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Aphonia	v.24.1	
Chills	v.24.1	
Cough	v.24.1	
Illness	v.24.1	
Oropharyngeal pain	v.24.1	5 Days
Pyrexia	v.24.1	
Vaginal abscess	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Vaginal infection	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04820998	0	2021-10-27	2021-10-27	MAH	202101367009	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
43 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown		Total		COVID-19 immunisation
ORENCIA	Suspect		Intravenous (not otherwise specified)	750.0 Milligram	Cyclical		Rheumatoid arthritis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Blood pressure increased	v.24.1	
Fall	v.24.1	
Upper limb fracture	v.24.1	
Urticaria	v.24.1	3 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04821007	0	2021-10-27	2021-10-27	MAH	202101367264	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
54 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETAMINOPHEN/OXYCODONE HYDROCHLORIDE	Concomitant	Tablets					Pain
ACTEMRA	Suspect	NOT SPECIFIED	Intravenous (not otherwise specified)	328.0 Milligram	1 every 1 Months	39.0 Days	Rheumatoid arthritis
COVID-19 VACCINE	Suspect		Intramuscular		Total	1.0 Days	COVID-19 immunisation
METHOTREXATE	Concomitant	NOT SPECIFIED	Subcutaneous	25.0 Milligram	1 every 1 Weeks		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Postmenopausal haemorrhage	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04821009	0	2021-10-27	2021-10-27	MAH	202101367151	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
25 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
HUMIRA	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous	40.0 Milligram			Colitis ulcerative

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.24.1	1 Months
Hypoaesthesia	v.24.1	1 Months
Pain	v.24.1	1 Months
Therapeutic product effect decreased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04821032	0	2021-10-27	2021-10-27	MAH	202101367247	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
57 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BETADERM	Concomitant	NOT SPECIFIED	Unknown				
CHLOROCRESOL;CLOBETASONE BUTYRATE	Concomitant		Unknown				
CICLOSPORIN	Concomitant	NOT SPECIFIED	Unknown				
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
DUPILUMAB	Suspect		Subcutaneous	300.0 Milligram		31.0 Days	Dermatitis atopic
EPIPEN 0.3MG/0.3ML AUTO-INJECTOR	Concomitant	SOLUTION INTRAMUSCULAR	Unknown				Eczema
PREDNISONE	Concomitant	NOT SPECIFIED	Unknown				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Cataract	v.24.1	
Condition aggravated	v.24.1	
Diarrhoea	v.24.1	1 Days
Eye pain	v.24.1	
Eye pruritus	v.24.1	
Eye swelling	v.24.1	
Feeling abnormal	v.24.1	1 Months
Headache	v.24.1	
Injury corneal	v.24.1	
Lacrimation increased	v.24.1	
Ocular hyperaemia	v.24.1	
Phobia of driving	v.24.1	
Vaccination site pain	v.24.1	1 Months
Vaccination site swelling	v.24.1	1 Months
Vision blurred	v.24.1	
Visual impairment	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04821033	0	2021-10-27	2021-10-27	MAH	202101367378	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
OCRELIZUMAB	Suspect		Intravenous (not otherwise specified)	300.0 Milligram			Relapsing-remitting multiple sclerosis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cellulitis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04821576	1	2021-10-27	2021-12-20	MAH	202101367297	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
70 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
MEPOLIZUMAB	Suspect		Subcutaneous	100.0 Milligram	Cyclical		Asthma

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dyspnoea	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04821910	2	2021-10-28	2021-12-24	MAH	CA2021222341	Study	Consumer/other non health professional

Serious report?
Serious

Death:	No	**Disability:**	No	**Congenital Anomaly:**	No
Life Threatening:	No	**Hospitalization:**	No	**Other Medically Important Conditions:**	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
88 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	
Linked	
Linked	E2B_03064993
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	E2B_03064993
Linked	
Linked	
Linked	
Linked	

Record Type	Link AER** Number
Linked	
Linked	
Linked	
Linked	E2B_03064993
Linked	E2B_05168939
Linked	
Linked	
Linked	
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				COVID-19 prophylaxis
INFLUENZA VACCINES	Suspect	NOT SPECIFIED	Unknown				Prophylaxis
MEPOLIZUMAB	Suspect		Subcutaneous	100.0 Milligram			Asthma

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Glaucoma	v.24.1	
Macular degeneration	v.24.1	
Neck pain	v.24.1	
Oxygen therapy	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04824693	4	2021-10-28	2021-12-02	MAH	2021TUS059997	Study	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
50 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AMLODIPINE	Concomitant	Tablets	Unknown				
APO-TRAMADOL	Concomitant	Tablets	Unknown				
CALCIUM CARBONATE	Concomitant	NOT SPECIFIED	Unknown				
CALCIUM SENNOSIDES A & B	Concomitant		Unknown				
COENZYME Q10	Concomitant	NOT SPECIFIED	Unknown				
COVID-19 VACCINE	Suspect		Unknown				Product used for unknown indication
ETHINYL ESTRADIOL/LEVONORGESTREL	Concomitant		Unknown				
GABAPENTIN	Concomitant	NOT SPECIFIED	Unknown				

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
IMMUNOGLOBULIN (HUMAN)	Suspect	Solution for infusion	Unknown	8.0 Gram	1 every 1 Weeks		Primary immunodeficiency syndrome
IMMUNOGLOBULIN (HUMAN)	Suspect		Unknown			365.0	Primary immunodeficiency syndrome
IMMUNOGLOBULIN (HUMAN)	Suspect	Solution for infusion	Unknown	8.0 Gram	1 every 1 Weeks		Primary immunodeficiency syndrome
JARDIANCE	Concomitant		Unknown				
MELATONIN	Concomitant	NOT SPECIFIED	Unknown				
METFORMIN	Concomitant		Unknown				
NORTRIPTYLINE HYDROCHLORIDE	Concomitant		Unknown				
OLANZAPINE	Concomitant	NOT SPECIFIED	Unknown				
OMEGA 3	Concomitant	Capsule	Unknown				
OMEPRAZOLE	Concomitant	NOT SPECIFIED	Unknown				
OXYBUTYNIN HYDROCHLORIDE	Concomitant		Unknown				
PERINDOPRIL	Concomitant	NOT SPECIFIED	Unknown				
PRAVASTATIN	Concomitant	Tablets	Unknown				
SEMAGLUTIDE	Concomitant	SOLUTION SUBCUTANEOUS	Unknown				
SERTRALINE HYDROCHLORIDE	Concomitant		Unknown				
SYNTHROID	Concomitant	NOT SPECIFIED	Unknown				
TRAZODONE	Concomitant	Tablets	Unknown				
VITAMIN D	Concomitant	Capsules	Unknown				
VITAMINS NOS	Concomitant		Unknown				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
COVID-19 immunisation	v.24.1	
Disturbance in attention	v.24.1	
Dizziness	v.24.1	
Fatigue	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Feeling cold	v.24.1	
Memory impairment	v.24.1	
Menstrual disorder	v.24.1	
Mental impairment	v.24.1	
Nervousness	v.24.1	
Pallor	v.24.1	
Product preparation issue	v.24.1	
Tooth infection	v.24.1	
Toothache	v.24.1	
Vaccination complication	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:09:42 AM
Initial Received Date:	2021-09-30 to 2021-12-30
Latest Received Date:	N/A
Total Number of Reports:	197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04824893	0	2021-10-28	2021-10-28	MAH	202101367333	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
69 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETAMINOPHEN	Concomitant	NOT SPECIFIED	Oral	650.0 Milligram			Premedication
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
DIPHENHYDRAMINE	Concomitant		Oral	50.0 Milligram			Premedication
METHYLPREDNISOLONE	Concomitant		Intravenous (not otherwise specified)	100.0 Milligram			Premedication
PREDNISONE	Concomitant	NOT SPECIFIED					
RITUXIMAB	Suspect		Intravenous (not otherwise specified)	500.0 Milligram	Cyclical		Microscopic polyangiitis
SEPTRA	Concomitant	Tablets					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cardiac disorder	v.24.1	
Dyspnoea	v.24.1	
Pericarditis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04824896	0	2021-10-28	2021-10-28	MAH	202101366952	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
80 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Duplicate	E2B_03742623

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CLADRIBINE	Concomitant	SOLUTION INTRAVENOUS					
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
RITUXIMAB	Suspect		Intravenous (not otherwise specified)				Hairy cell leukaemia
ZELBORAF FILM-COATED TABLET	Suspect	Tablets	Oral	960.0 Milligram	2 every 1 Days		Hairy cell leukaemia

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Agranulocytosis	v.24.1	
Anaemia	v.24.1	
Asthenia	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
BRAF gene mutation	v.24.1	
Benign prostatic hyperplasia	v.24.1	
Dyspnoea exertional	v.24.1	
Fall	v.24.1	
Fatigue	v.24.1	
Femur fracture	v.24.1	
Gastrointestinal lymphoma	v.24.1	
Injection site pain	v.24.1	1 Days
Liver palpable	v.24.1	
Off label use	v.24.1	
Osteoporosis	v.24.1	
Overgrowth bacterial	v.24.1	
Pancytopenia	v.24.1	
Pruritus	v.24.1	
Rash	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04824931	0	2021-10-28	2021-10-28	MAH	202101374376	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
42 Years	Female		83 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
REMICADE	Suspect	POWDER FOR SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	400.0 Milligram	Cyclical		Crohn's disease

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal distension	v.24.1	
Flatulence	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:09:42 AM
Initial Received Date:	2021-09-30 to 2021-12-30
Latest Received Date:	N/A
Total Number of Reports:	197 Report(s)

Report Information

***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04824937	0	2021-10-28	2021-10-28	MAH	202101374251	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
46 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total	31.0 Days	COVID-19 immunisation
HUMIRA	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous	40.0 Milligram	Cyclical		Rheumatoid arthritis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Gait disturbance	v.24.1	
Rheumatoid arthritis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04824939	0	2021-10-28	2021-10-28	MAH	202101380335	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
83 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Duplicate	E2B_04595174

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
MEPOLIZUMAB	Suspect		Subcutaneous	100.0 Milligram			Asthma

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anxiety	v.24.1	
Constipation	v.24.1	
Illness	v.24.1	
Pyrexia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04824943	1	2021-10-28	2021-11-01	MAH	202101374028	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
70 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CALCIUM	Concomitant	NOT SPECIFIED	Unknown				
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
DESOXIMETASONE	Concomitant	NOT SPECIFIED	Unknown				
HYDROXYCHLOROQUINE SULFATE	Concomitant		Unknown				
ORENCIA	Suspect		Intravenous (not otherwise specified)	750.0 Milligram	Cyclical		Rheumatoid arthritis
RISEDRONATE SODIUM	Concomitant	NOT SPECIFIED	Unknown				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood pressure systolic increased	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Carpal tunnel syndrome	v.24.1	
Feeling abnormal	v.24.1	
Mouth ulceration	v.24.1	
Myalgia	v.24.1	
Therapeutic response decreased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04824956	0	2021-10-28	2021-10-28	MAH	202101380312	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
80 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
MEPOLIZUMAB	Suspect		Subcutaneous	100.0 Milligram			Asthma

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Breath sounds abnormal	v.24.1	
Chronic obstructive pulmonary disease	v.24.1	
Cough	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Infection	v.24.1	
Lower respiratory tract infection	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Product dose omission issue	v.24.1	
Respiratory tract congestion	v.24.1	
Sputum discoloured	v.24.1	
Wheezing	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04824962	1	2021-10-28	2021-12-09	MAH	202101380653	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
69 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
HUMIRA	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous	40.0 Milligram	Cyclical		Crohn's disease

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Antibody test positive	v.24.1	
Arthritis	v.24.1	
Asthenia	v.24.1	
Condition aggravated	v.24.1	
Dyspnoea	v.24.1	
Headache	v.24.1	
Loss of personal independence in daily activities	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Malaise	v.24.1	
Psoriasis	v.24.1	
Therapeutic product effect decreased	v.24.1	
Therapeutic response shortened	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04824977	0	2021-10-28	2021-10-28	MAH	202101374385	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
50 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETAMINOPHEN	Concomitant	NOT SPECIFIED					
BACLOFEN	Concomitant	NOT SPECIFIED					Muscle spasms
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
MELATONIN	Concomitant	NOT SPECIFIED					
OCRELIZUMAB	Suspect		Intravenous (not otherwise specified)	300.0 Milligram			Primary progressive multiple sclerosis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	
Initial insomnia	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Limb immobilisation	v.24.1	
Poor quality sleep	v.24.1	
Pyrexia	v.24.1	
Sensory loss	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04824997	1	2021-10-28	2021-12-06	MAH	202101380379	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
92 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown		Total		COVID-19 immunisation
MEPOLIZUMAB	Suspect		Subcutaneous	100.0 Milligram			Asthma

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood pressure increased	v.24.1	
Cellulitis	v.24.1	
Fall	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Limb injury	v.24.1	
Ocular hyperaemia	v.24.1	
Suture insertion	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Wheezing	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04825902	1	2021-10-28	2021-11-01	MAH	202101374241	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
73 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Duplicate	E2B_04694236

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
MEPOLIZUMAB	Suspect		Subcutaneous	100.0 Milligram			Asthma

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Amnesia	v.24.1	
Anxiety	v.24.1	
Balance disorder	v.24.1	
Chronic obstructive pulmonary disease	v.24.1	
Deafness	v.24.1	
Depression	v.24.1	
Dizziness	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dry skin	v.24.1	
Dyspnoea	v.24.1	
Erythema	v.24.1	
Neoplasm malignant	v.24.1	
Pain	v.24.1	
Product dose omission issue	v.24.1	
Productive cough	v.24.1	
Pruritus	v.24.1	
Rash	v.24.1	
Renal cancer	v.24.1	
Therapeutic product effect incomplete	v.24.1	
Tinnitus	v.24.1	
Tooth disorder	v.24.1	
Tremor	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04825931	1	2021-10-28	2021-12-13	MAH	202101380480	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
60 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
REMICADE	Suspect	Solution for infusion	Intravenous (not otherwise specified)	800.0 Milligram	Cyclical		Crohn's disease
REMICADE	Suspect	POWDER FOR SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)				Crohn's disease

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.24.1	2 Months
Drug ineffective	v.24.1	2 Months
Pneumonia	v.24.1	2 Months

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04825955	0	2021-10-28	2021-10-28	MAH	202101380517	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
24 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
TALTZ	Suspect		Unknown	80.0 Milligram			Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arrhythmia	v.24.1	
Arthralgia	v.24.1	
Back pain	v.24.1	
Headache	v.24.1	
Myalgia	v.24.1	
Neck pain	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pain	v.24.1	
Pain in extremity	v.24.1	
Sleep disorder	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04826190	1	2021-10-28	2021-11-08	MAH	2019SA257569	Study	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
83 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				Immunisation
COZAAR	Concomitant	Tablets	Oral	25.0 Milligram	1 every 12 Hours		Hypertension
DOXEPIN HYDROCHLORIDE	Concomitant		Oral	50.0 Milligram			Depression
DUPIXENT	Suspect	Solution	Subcutaneous	600.0 Milligram	Total	1.0 Days	Dermatitis atopic
DUPIXENT	Suspect	Solution for injection	Subcutaneous	300.0 Milligram	1 every 2 Weeks	0.0	Dermatitis atopic
DUPIXENT	Suspect	Solution for injection	Subcutaneous	300.0 Milligram	1 every 2 Weeks		Dermatitis atopic
HYDROCHLOROTHIAZIDE	Concomitant	Tablets	Oral				Hypertension
SYNTHROID	Concomitant	NOT SPECIFIED	Oral				Hypothyroidism
TENORMIN	Concomitant	Tablets	Oral				Hypertension

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
VITAMIN D3	Concomitant		Oral		1 every 1 Weeks		Osteoporosis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cardiac discomfort	v.24.1	
Eye pruritus	v.24.1	
Fatigue	v.24.1	
Fatigue	v.24.1	
Hypotension	v.24.1	
Quality of life decreased	v.24.1	
Therapeutic response decreased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04830371	0	2021-10-29	2021-10-29	MAH	202101380324	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
34 Years	Male		126 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
OCRELIZUMAB	Suspect		Intravenous (not otherwise specified)	300.0 Milligram			Relapsing-remitting multiple sclerosis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal discomfort	v.24.1	
Back pain	v.24.1	
Discomfort	v.24.1	
Headache	v.24.1	
Hypoaesthesia	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Nasopharyngitis	v.24.1	
Pain	v.24.1	
Pain in extremity	v.24.1	
Pericarditis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04830373	1	2021-10-29	2021-12-07	MAH	202101380407	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
56 Years	Male		100 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
PREDNISONE	Concomitant	NOT SPECIFIED	Oral				
PREDNISONE	Concomitant	Capsules	Oral	4.0 Milligram			
STELARA	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous	90.0 Milligram	1 every 1 Months		Colitis ulcerative

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain	v.24.1	
Defaecation urgency	v.24.1	
Diarrhoea	v.24.1	
Eructation	v.24.1	
Flatulence	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Frequent bowel movements	v.24.1	
Haematochezia	v.24.1	
Off label use	v.24.1	
Pain in jaw	v.24.1	
Product use issue	v.24.1	
Toothache	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04830374	0	2021-10-29	2021-10-29	MAH	202101380580	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
60 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
HUMIRA	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous	40.0 Milligram	1 every 1 Weeks		Ankylosing spondylitis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	
Lymphadenopathy	v.24.1	
Nausea	v.24.1	
Pain in extremity	v.24.1	
Renal disorder	v.24.1	
Single functional kidney	v.24.1	
Swelling	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04830409	2	2021-10-29	2021-12-20	MAH	202101374268	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
80 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
ESBRIET	Suspect	Tablet	Oral	534.0 Milligram	3 every 1 Days	31.0 Days	Idiopathic pulmonary fibrosis
IRBESARTAN	Concomitant	Tablets	Unknown				
PLANTAGO OVATA	Concomitant						
RABEPRAZOLE	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain upper	v.24.1	
Blood sodium decreased	v.24.1	1 Days
Dehydration	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Gastrointestinal pain	v.24.1	
Intentional dose omission	v.24.1	
Nausea	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04831127	1	2021-10-29	2021-11-15	MAH	20211030786	Study	Pharmacist

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
68 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Duplicate	E2B_05290841

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
APALUTAMIDE	Suspect		Oral	240.0 Milligram	4 every 1 Days		Hormone-refractory prostate cancer
COVID-19 VACCINE	Suspect		Unknown				Product used for unknown indication
INFLUENZA VACCINES	Suspect		Unknown				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Rash	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04835255	1	2021-11-01	2021-12-23	MAH	CA2021AMR203820	Study	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
71 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_04273686
Linked	E2B_04273686

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				Product used for unknown indication, COVID-19 prophylaxis
COVID-19 VACCINE	Suspect		Unknown				Product used for unknown indication, COVID-19 prophylaxis
MEPOLIZUMAB	Suspect	Solution for injection in pre-filled pen	Subcutaneous	100.0 Milligram			Asthma
MEPOLIZUMAB	Suspect		Subcutaneous	100.0 Milligram			Asthma

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Breath sounds abnormal	v.24.1	
Cough	v.24.1	
Dyspnoea	v.24.1	
Pneumonia	v.24.1	
Sputum discoloured	v.24.1	
Wheezing	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04836381	0	2021-11-01	2021-11-01	MAH	202101390210	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
74 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETYLSALICYLIC ACID	Concomitant		Unknown				
ADVAIR	Concomitant	NOT SPECIFIED	Unknown				
AMLODIPINE	Concomitant	Tablets	Unknown				
ATIVAN	Concomitant	NOT SPECIFIED	Unknown				
BACLOFEN	Concomitant	NOT SPECIFIED	Unknown				
BIFIDOBACTERIUM ANIMALIS SUBSP. ANIMALIS/LACTOBACILLUS ACIDOPHILUS	Concomitant		Unknown				
CARBAMAZEPINE	Concomitant	NOT SPECIFIED	Unknown				
COVID-19 VACCINE	Suspect		Unknown		Total		COVID-19 immunisation
CYANOCOBALAMIN	Concomitant		Unknown				
GABAPENTIN	Concomitant	NOT SPECIFIED	Unknown				

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
GRAVOL	Concomitant	NOT SPECIFIED	Unknown				
IRON	Concomitant		Unknown				
MEPOLIZUMAB	Suspect		Subcutaneous	100.0 Milligram			Asthma
METONIA	Concomitant	NOT SPECIFIED	Unknown				
MONTELUKAST SODIUM	Concomitant		Unknown				
NIACIN	Concomitant	NOT SPECIFIED	Unknown				
NICODERM	Concomitant	PATCH	Unknown				
PANTOPRAZOLE MAGNESIUM	Concomitant		Unknown				
RISEDRONATE	Concomitant	Tablets	Unknown				
ROSUVASTATIN CALCIUM	Concomitant		Unknown				
SANDOZ CANDESARTAN PLUS	Concomitant	Tablets	Unknown				
SPIRIVA	Concomitant	NOT SPECIFIED	Unknown				
VENTOLIN [SALBUTAMOL]	Concomitant		Unknown				
VITAMIN C [ASCORBIC ACID]	Concomitant		Unknown				
VITAMIN D3	Concomitant	Capsules	Unknown				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthritis	v.24.1	
Contusion	v.24.1	
Gait inability	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Intestinal ischaemia	v.24.1	
Multiple sclerosis	v.24.1	
Muscle spasms	v.24.1	
Vaccination complication	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04836398	0	2021-11-01	2021-11-01	MAH	202101390401	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
40 Years	Female		71 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown		Total		COVID-19 immunisation
STELARA	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous	90.0 Milligram			Crohn's disease

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain	v.24.1	
Back disorder	v.24.1	
Diarrhoea	v.24.1	
Fungal rhinitis	v.24.1	
Joint noise	v.24.1	
Malaise	v.24.1	
Myalgia	v.24.1	1 Months

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Oral candidiasis	v.24.1	
Road traffic accident	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:09:42 AM
Initial Received Date:	2021-09-30 to 2021-12-30
Latest Received Date:	N/A
Total Number of Reports:	197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04836400	0	2021-11-01	2021-11-01	MAH	202101389490	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
39 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CARBAMAZEPINE	Concomitant	NOT SPECIFIED	Unknown	200.0 Milligram	2 every 1 Days		Seizure
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
DULOXETINE HYDROCHLORIDE	Concomitant		Unknown	60.0 Milligram	1 every 1 Days		
METHYLPREDNISOLONE SODIUM SUCCINATE	Concomitant						
OCRELIZUMAB	Suspect		Intravenous (not otherwise specified)	300.0 Milligram			Relapsing-remitting multiple sclerosis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Epilepsy	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Heart rate increased	v.24.1	
Hypoaesthesia	v.24.1	
Infusion related reaction	v.24.1	
Insomnia	v.24.1	
Pain in extremity	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04836401	0	2021-11-01	2021-11-01	MAH	202101390136	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
71 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ATENOLOL	Concomitant	Tablets					
COLCHICINE	Concomitant	Tablets					
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
GABAPENTIN	Concomitant	NOT SPECIFIED					
GLICLAZIDE	Concomitant	Tablets					
HYDROMORPHONE	Concomitant	NOT SPECIFIED					
LANREOTIDE ACETATE	Suspect		Subcutaneous	120.0 Milligram	1 every 1 Months		Neuroendocrine tumour
PANTOPRAZOLE	Concomitant	NOT SPECIFIED					
SYNTHROID	Concomitant	NOT SPECIFIED					
XARELTO	Concomitant	Coated tablet					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal distension	v.24.1	
Abdominal pain	v.24.1	
Abdominal rigidity	v.24.1	
Back pain	v.24.1	
Decreased appetite	v.24.1	
Diarrhoea	v.24.1	
Fall	v.24.1	
Fatigue	v.24.1	
Flatulence	v.24.1	
Hypersomnia	v.24.1	
Pleurisy	v.24.1	
Pyrexia	v.24.1	
Restlessness	v.24.1	
Urinary tract infection	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04836425	0	2021-11-01	2021-11-01	MAH	202101390331	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
60 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown		Total		COVID-19 immunisation
STELARA	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous	90.0 Milligram			Crohn's disease

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain	v.24.1	
Diarrhoea	v.24.1	
Frequent bowel movements	v.24.1	
General physical health deterioration	v.24.1	
Haematochezia	v.24.1	
Malaise	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:09:42 AM
Initial Received Date:	2021-09-30 to 2021-12-30
Latest Received Date:	N/A
Total Number of Reports:	197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04836427	0	2021-11-01	2021-11-01	MAH	202101389244	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AMOXICILLIN	Concomitant	NOT SPECIFIED					
COVID-19 VACCINE	Suspect		Unknown		Total		COVID-19 immunisation
OCRELIZUMAB	Suspect		Intravenous (not otherwise specified)	600.0 Milligram			Relapsing-remitting multiple sclerosis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Balance disorder	v.24.1	
Clumsiness	v.24.1	
Cystitis	v.24.1	
Fall	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.24.1	
Gait disturbance	v.24.1	
Hypersomnia	v.24.1	
Nasal disorder	v.24.1	
Stress fracture	v.24.1	
Urinary tract infection	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04836430	1	2021-11-01	2021-12-09	MAH	202101389183	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
49 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
OCRELIZUMAB	Suspect		Intravenous (not otherwise specified)	300.0 Milligram			Relapsing-remitting multiple sclerosis
PREDNISONE	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal discomfort	v.24.1	
Cerebral haemorrhage	v.24.1	
Fall	v.24.1	
Gait disturbance	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.24.1	
Helicobacter test positive	v.24.1	
Illness	v.24.1	
Influenza	v.24.1	
Malaise	v.24.1	
Nausea	v.24.1	
Neutrophil count increased	v.24.1	
Pain	v.24.1	
Paraesthesia	v.24.1	
Pyrexia	v.24.1	
Tremor	v.24.1	
Vomiting	v.24.1	
Weight decreased	v.24.1	
White blood cell count increased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:09:42 AM
Initial Received Date:	2021-09-30 to 2021-12-30
Latest Received Date:	N/A
Total Number of Reports:	197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04836492	1	2021-11-01	2021-12-21	MAH	202101389514	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
22 Years	Male		62 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
IDURSULFASE	Suspect		Unknown	5.0 Dosage forms	1 every 1 Weeks		Mucopolysaccharidosis II
LEVETIRACETAM	Concomitant	Tablet		1500.0 Milligram	2 every 1 Days		Seizure, Epilepsy
LEVETIRACETAM	Concomitant	Tablets		1125.0 Milligram	2 every 1 Days		Seizure, Epilepsy

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abnormal behaviour	v.24.1	
Asthenia	v.24.1	
Body temperature decreased	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bowel movement irregularity	v.24.1	
Catheter site swelling	v.24.1	
Cold sweat	v.24.1	
Condition aggravated	v.24.1	
Crying	v.24.1	
Decreased appetite	v.24.1	
Ear infection	v.24.1	
Epilepsy	v.24.1	
Erythema	v.24.1	
Excessive cerumen production	v.24.1	
Eyelid disorder	v.24.1	
Fatigue	v.24.1	
Gait disturbance	v.24.1	
Hot flush	v.24.1	
Hypotension	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Incorrect product administration duration	v.24.1	
Increased tendency to bruise	v.24.1	
Infusion related reaction	v.24.1	
Lip discolouration	v.24.1	
Medication error	v.24.1	
Muscle mass	v.24.1	
Poor quality sleep	v.24.1	
Poor venous access	v.24.1	
Rash erythematous	v.24.1	
Seizure	v.24.1	
Skin discolouration	v.24.1	
Somnolence	v.24.1	
Syncope	v.24.1	
Temperature difference of extremities	v.24.1	
Vaccination site bruising	v.24.1	
Vaccination site erythema	v.24.1	
Vaccination site oedema	v.24.1	
Vaccination site swelling	v.24.1	
Weight increased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04836503	1	2021-11-01	2021-12-03	MAH	202101389545	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
64 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
NINTEDANIB ESILATE	Suspect	Capsules	Oral		2 every 1 Days		Idiopathic pulmonary fibrosis
NINTEDANIB ESILATE	Suspect		Oral	100.0 Milligram	2 every 1 Days		Idiopathic pulmonary fibrosis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal distension	v.24.1	
Abdominal pain upper	v.24.1	
Alanine aminotransferase increased	v.24.1	
Asthenia	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood pressure increased	v.24.1	
Dizziness	v.24.1	
Flatulence	v.24.1	
Hepatic steatosis	v.24.1	
Liver function test abnormal	v.24.1	
Malaise	v.24.1	
Nausea	v.24.1	
Pain	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04836580	1	2021-11-01	2021-11-26	MAH	202101390262	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
79 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
MEPOLIZUMAB	Suspect		Subcutaneous	100.0 Milligram			Asthma

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Nerve compression	v.24.1	
Pneumonia	v.24.1	
Sciatica	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:09:42 AM
Initial Received Date:	2021-09-30 to 2021-12-30
Latest Received Date:	N/A
Total Number of Reports:	197 Report(s)

Report Information

***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04846423	0	2021-11-03	2021-11-03	MAH	20211041870	Study	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				COVID-19 prophylaxis
REMICADE	Suspect	POWDER FOR SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)				Crohn's disease

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Exposure during pregnancy	v.24.1	
Infusion related reaction	v.24.1	
Nausea	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04861511	0	2021-11-08	2021-11-08	MAH	21K-028-4142019-00	Study	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
43 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_04865457
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular			1.0 Months	COVID-19 immunisation
RISANKIZUMAB	Suspect		Subcutaneous	150.0 Milligram	1 every 12 Weeks		Psoriasis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Drug ineffective	v.24.1	
Psoriasis	v.24.1	
Therapeutic response shortened	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04865457	0	2021-11-09	2021-11-09	MAH	13P-028-1118092-00	Study	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
43 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_04861511

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular			1.0 Months	COVID-19 immunisation
HUMIRA	Suspect	Solution for injection in pre-filled pen	Subcutaneous		1 every 1 Weeks	960.0	Psoriasis
HUMIRA	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous		1 every 2 Weeks	4.0 Years	Psoriasis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Drug ineffective	v.24.1	
Psoriasis	v.24.1	
Psoriasis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04909673	0	2021-11-18	2021-11-18	MAH	CA202032753	Study	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
72 Years	Female		84 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CELEXA [CELECOXIB]	Concomitant						Product used for unknown indication
COVID-19 VACCINE	Suspect		Unknown				COVID-19 immunisation
ELTROXIN	Concomitant	Tablets					Product used for unknown indication
IMMUNOGLOBULIN (HUMAN)	Suspect	Solution for infusion	Unknown	10.0 Gram	1 every 1 Weeks		Secondary immunodeficiency
IMMUNOGLOBULIN (HUMAN)	Suspect	Solution for infusion	Unknown	10.0 Gram	1 every 1 Weeks		Secondary immunodeficiency

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
IMMUNOGLOBULIN (HUMAN)	Suspect		Unknown	10.0 Gram	1 every 1 Weeks		Secondary immunodeficiency
RABEPRAZOLE	Concomitant						Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthropathy	v.24.1	
Chemotherapy	v.24.1	
Diarrhoea	v.24.1	
Infusion site erythema	v.24.1	
Infusion site pain	v.24.1	
Infusion site pruritus	v.24.1	
Nausea	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04914899	1	2021-11-19	2021-11-21	MAH	2021BI01067426	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
39 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				COVID-19 prophylaxis
TYSABRI	Suspect	Unknown	Intravenous (not otherwise specified)	300.0 Milligram	1 every 5 Weeks		Multiple sclerosis
TYSABRI	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	300.0 Milligram	1 every 4 Weeks	8.0 Years	Multiple sclerosis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Seizure	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04916513	1	2021-11-19	2021-11-26	MAH	20211133862	Study	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
56 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				COVID-19 prophylaxis
REMICADE	Suspect	POWDER FOR SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	850.0 Milligram	1 every 8 Weeks		Colitis ulcerative

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cellulitis	v.24.1	
Headache	v.24.1	
Localised infection	v.24.1	
Pneumonia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:09:42 AM
Initial Received Date:	2021-09-30 to 2021-12-30
Latest Received Date:	N/A
Total Number of Reports:	197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04922196	0	2021-11-22	2021-11-22	MAH	202101555941	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
60 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Drug ineffective	v.24.1	
Suspected COVID-19	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04922247	0	2021-11-22	2021-11-22	MAH	202101555940	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
65 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Drug ineffective	v.24.1	
Suspected COVID-19	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04923792	0	2021-11-23	2021-11-23	MAH	CA2021238144	Study	Consumer/other non health professional

Serious report?
Serious

Death:	No	**Disability:**	No	**Congenital Anomaly:**	No
Life Threatening:	No	**Hospitalization:**	Yes	**Other Medically Important Conditions:**	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
72 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	E2B_02885101
Linked	
Linked	
Linked	E2B_01975382
Linked	
Linked	
Linked	E2B_03122723
Linked	E2B_03190895
Linked	E2B_03977870
Linked	
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				Product used for unknown indication
MEPOLIZUMAB	Suspect		Subcutaneous	100.0 Milligram			Asthma

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Haematochezia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:09:42 AM
Initial Received Date:	2021-09-30 to 2021-12-30
Latest Received Date:	N/A
Total Number of Reports:	197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04925387	0	2021-11-23	2021-11-23	MAH	2956335	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BENADRYL	Concomitant	NOT SPECIFIED					
COVID-19 VACCINE	Suspect		Unknown				Product used for unknown indication
FLOVENT	Concomitant	NOT SPECIFIED					
OCRELIZUMAB	Suspect		Intravenous (not otherwise specified)	300.0 Milligram	1 every 14 Days		Relapsing-remitting multiple sclerosis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Erythema	v.24.1	
Fatigue	v.24.1	
Immunodeficiency	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Inflammation	v.24.1	
Pneumonia	v.24.1	
Rash	v.24.1	
Skin plaque	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04929158	0	2021-11-24	2021-11-24	MAH	BL-2020-029390	Study	

Serious report?	Death:	No	Disability:	Yes	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
44 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				COVID-19 prophylaxis
SILIQ 2 SINGLE USE PREFILLED SYRINGES	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous	210.0 Milligram	1 every 1 Weeks	1.0 Months	Psoriasis
SILIQ 2 SINGLE USE PREFILLED SYRINGES	Suspect	Solution for injection	Subcutaneous	210.0 Milligram	1 every 2 Weeks		Psoriasis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anxiety	v.24.1	0
Depression	v.24.1	
Disability	v.24.1	
Dizziness	v.24.1	
Dyspnoea	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Emotional disorder	v.24.1	
Fatigue	v.24.1	
Headache	v.24.1	0
Palpitations	v.24.1	
Somnolence	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04932156	1	2021-11-24	2021-12-13	MAH	20211139352	Study	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
52 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	
Linked	
Linked	
Linked	E2B_01445314
Linked	
Linked	
Linked	E2B_01445314
Linked	
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				COVID-19 prophylaxis

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
REMICADE	Suspect	POWDER FOR SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	500.0 Milligram			Crohn's disease

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Atypical pneumonia	v.24.1	
Crohn's disease	v.24.1	
Respiratory tract infection	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04932193	0	2021-11-24	2021-11-24	MAH	202101625217	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
51 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
STELARA	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous				Crohn's disease

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Lower respiratory tract infection	v.24.1	
Pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04932201	1	2021-11-24	2021-12-21	MAH	202101625196	Study	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
73 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
MEPOLIZUMAB	Suspect		Subcutaneous	100.0 Milligram			Asthma

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypoglycaemia	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Pneumonia	v.24.1	
Product dose omission issue	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04932315	1	2021-11-24	2021-12-16	MAH	20211036902	Study	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
62 Years	Female		61 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				COVID-19 prophylaxis
REMICADE	Suspect	POWDER FOR SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	300.0 Milligram	1 every 4 Weeks		Rheumatoid arthritis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Body temperature increased	v.24.1	
Cough	v.24.1	
Dysphonia	v.24.1	
Head discomfort	v.24.1	
Illness	v.24.1	
Lower respiratory tract infection	v.24.1	
Nasopharyngitis	v.24.1	
Pneumonia	v.24.1	
Pneumonitis	v.24.1	
Rhinorrhoea	v.24.1	
Sinus disorder	v.24.1	
Skin discolouration	v.24.1	
Sputum discoloured	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04943076	0	2021-11-26	2021-11-26	MAH	202101646982	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
28 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ALEMTUZUMAB	Suspect	SOLUTION INTRAVENOUS	Intravenous drip	12.0 Milligram	1 every 1 Days	3.0 Days	Relapsing-remitting multiple sclerosis
AZATHIOPRINE SODIUM	Concomitant		Unknown				
CALCIUM	Concomitant	NOT SPECIFIED	Unknown				
CETIRIZINE HYDROCHLORIDE	Concomitant		Unknown	10.0 Milligram			
COVID-19 VACCINE	Suspect		Unknown		Total		COVID-19 immunisation
ENTOCORT	Concomitant	CAPSULE, SUSTAINED-RELEASE	Unknown				
FINGOLIMOD HYDROCHLORIDE	Concomitant		Unknown				

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
METHYLPREDNISOLONE	Concomitant		Unknown	500.0 Milligram			
RANITIDINE	Concomitant		Unknown	150.0 Milligram			
TYLENOL	Concomitant	NOT SPECIFIED	Unknown	1.0 Gram			
VALACYCLOVIR	Concomitant	NOT SPECIFIED	Unknown	500.0 Milligram			
VITAMIN D	Concomitant	NOT SPECIFIED	Unknown				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Contusion	v.24.1	
Immune thrombocytopenia	v.24.1	
Influenza	v.24.1	
Menstruation irregular	v.24.1	
Nasopharyngitis	v.24.1	
Pain	v.24.1	
Platelet count decreased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04943570	1	2021-11-26	2021-12-21	MAH	202101646928	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
75 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACTEMRA	Suspect	Solution for injection in pre-filled syringe	Unknown				Vasculitis, Giant cell arteritis
ACTEMRA	Suspect	NOT SPECIFIED	Subcutaneous	162.0 Milligram	1 every 1 Weeks	365.0 Days	Vasculitis, Giant cell arteritis
ACTEMRA	Suspect	Solution for injection in pre-filled syringe	Subcutaneous	162.0 Milligram	1 every 1 Weeks		Vasculitis, Giant cell arteritis
ACTEMRA	Suspect		Unknown				Vasculitis, Giant cell arteritis
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
DIOVAN	Concomitant	NOT SPECIFIED					
DOMPERIDONE	Concomitant	Tablets	Unknown				Vomiting
FELODIPINE	Concomitant	TABLET (EXTENDED-RELEASE)	Unknown	5.0 Milligram			
LEVOTHYROXINE SODIUM	Concomitant	NOT SPECIFIED	Oral	88.0 Microgram			

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
METFORMIN HYDROCHLORIDE/SITAGLIPTIN PHOSPHATE MONOHYDRATE	Concomitant		Unknown	1000.0 Milligram			
PANTOPRAZOLE	Concomitant	NOT SPECIFIED	Unknown	40.0 Milligram			
PREDNISONE	Concomitant	NOT SPECIFIED	Oral	5.0 Milligram			
PREDNISONE	Concomitant		Unknown	20.0 Milligram	1 every 1 Days		
PREDNISONE	Concomitant		Unknown			305.0 Days	
RISEDRONATE SODIUM	Concomitant	NOT SPECIFIED					
RISEDRONATE SODIUM	Concomitant						
SIMVASTATIN	Concomitant	Tablets	Unknown	10.0 Milligram			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain	v.24.1	
Alanine aminotransferase increased	v.24.1	
Angiopathy	v.24.1	
Arthralgia	v.24.1	
Aspartate aminotransferase increased	v.24.1	
Blood creatinine increased	v.24.1	
Blood iron decreased	v.24.1	
Bone pain	v.24.1	
C-reactive protein increased	v.24.1	
Cystitis	v.24.1	
Diarrhoea	v.24.1	
Dysuria	v.24.1	
Ear pain	v.24.1	
Eczema	v.24.1	
Erythema	v.24.1	
Fatigue	v.24.1	
Glomerular filtration rate decreased	v.24.1	
Glomerular filtration rate increased	v.24.1	
Haemoglobin decreased	v.24.1	
Headache	v.24.1	
Joint swelling	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Malaise	v.24.1	
Nasal congestion	v.24.1	
Nasopharyngitis	v.24.1	
Nausea	v.24.1	
Ophthalmic migraine	v.24.1	
Oral herpes	v.24.1	
Pain	v.24.1	
Pain in extremity	v.24.1	
Pain of skin	v.24.1	
Paranasal sinus inflammation	v.24.1	
Productive cough	v.24.1	
Pruritus	v.24.1	
Psoriasis	v.24.1	
Rash	v.24.1	
Rash vesicular	v.24.1	
Red blood cell count decreased	v.24.1	
Skin reaction	v.24.1	
Tooth disorder	v.24.1	
Toothache	v.24.1	
Urticaria	v.24.1	
Visual impairment	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04943577	0	2021-11-26	2021-11-26	MAH	202101647001	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
30 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
HUMIRA	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous	40.0 Milligram		336.0 Days	Ankylosing spondylitis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Back pain	v.24.1	
Pain	v.24.1	
Tonsillitis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04949516	0	2021-11-29	2021-11-29	MAH	202101654766	Study	

Serious report?	Death:	Yes	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
56 Years	Female			Fatal

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COMIRNATY VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Unknown		Total		COVID-19 immunisation
COVID-19 VACCINE	Suspect		Unknown		Total		COVID-19 immunisation
MEPOLIZUMAB	Suspect		Subcutaneous	100.0 Milligram			Asthma

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthma	v.24.1	
Product dose omission issue	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04950093	0	2021-11-29	2021-11-29	MAH	21K-028-4176191-00	Study	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
64 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular			0.0	COVID-19 immunisation
COVID-19 VACCINE	Suspect		Intramuscular			0.0	COVID-19 immunisation
COVID-19 VACCINE	Suspect		Intramuscular			0.0	COVID-19 immunisation
RINVOQ	Suspect	TABLET (EXTENDED-RELEASE)	Oral	15.0 Milligram	1 every 1 Days		Rheumatoid arthritis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Autoimmune disorder	v.24.1	
Pain	v.24.1	
Weight bearing difficulty	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04954816	0	2021-11-30	2021-11-30	MAH	202101655002	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
40 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown		Total		COVID-19 immunisation
GIVOSIRAN SODIUM	Suspect	NOT SPECIFIED	Subcutaneous	2.5 mg/kg			Porphyria acute
IRON	Concomitant						
LIFITEGRAST	Concomitant						
PIMECROLIMUS	Concomitant						
VITAMIN D	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pain in extremity	v.24.1	
Platelet count decreased	v.24.1	
Porphyria acute	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04954821	0	2021-11-30	2021-11-30	MAH	202101646957	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
47 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
REMICADE	Suspect	POWDER FOR SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)				Colitis ulcerative

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Colitis ulcerative	v.24.1	
Endocarditis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04954829	0	2021-11-30	2021-11-30	MAH	202101603210	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
75 Years	Female		40 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETYLSALICYLIC ACID	Concomitant	NOT SPECIFIED	Unknown	81.0 Milligram	1 every 1 Days		
AMLODIPINE;ATORVASTATIN	Concomitant		Unknown		1 every 1 Days		
ARNICA MONTANA	Concomitant	Cream	Topical		1 every 1 Days		
ATORVASTATIN CALCIUM	Concomitant	Tablets	Unknown	10.0 Milligram			
BISOPROLOL	Concomitant		Unknown	5.0 Milligram	1 every 1 Days		
CALCIUM	Concomitant	NOT SPECIFIED	Unknown	500.0 Milligram	1 every 1 Days		
CANNABIS SATIVA	Concomitant		Unknown		1 every 1 Days		
CLOPIDOGREL	Concomitant	Tablets	Unknown	75.0 Milligram	1 every 1 Days		
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
EPOETIN ALFA	Concomitant						
ERGOCALCIFEROL	Concomitant	NOT SPECIFIED					
GLICLAZIDE	Concomitant	Tablets	Unknown	30.0 Milligram	1 every 1 Days		

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
IBUPROFEN	Concomitant	NOT SPECIFIED	Unknown	400.0 Milligram	2 every 1 Days		Arthralgia
JANUVIA	Concomitant	NOT SPECIFIED	Unknown	100.0 Milligram	1 every 1 Days		
LIPITOR	Concomitant	NOT SPECIFIED	Unknown	10.0 Milligram	1 every 1 Days		
METFORMIN	Concomitant	Tablet	Unknown	500.0 Milligram			
METFORMIN	Concomitant	Tablet	Unknown	500.0 Milligram	1 every 1 Days		
OXYGEN	Concomitant	Gas for inhalation					
PANTOPRAZOLE	Concomitant	NOT SPECIFIED	Unknown	40.0 Milligram	1 every 1 Days		
PREDNISONE	Concomitant	NOT SPECIFIED					
RISEDRONATE SODIUM	Concomitant	NOT SPECIFIED					
RITUXIMAB	Suspect		Intravenous (not otherwise specified)	1000.0 Milligram			Rheumatoid arthritis
TECTA	Concomitant	NOT SPECIFIED	Unknown	40.0 Milligram	1 every 1 Days		
TYLENOL #1 (CAFFEINE/CODEINE PHOSPHATE/PARACETAMOL)	Suspect	Tablets	Unknown				Product used for unknown indication
TYLENOL EXTRA STRENGTH	Concomitant	Tablet	Oral		2 every 1 Days		
TYLENOL EXTRA STRENGTH	Concomitant	Tablets	Oral		3 every 1 Days		
UBIDECARENONE	Concomitant						
UBIDECARENONE	Concomitant		Unknown		1 every 1 Days		
VITAMIN C [ASCORBIC ACID]	Concomitant		Unknown	1.0 Dosage forms			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anion gap decreased	v.24.1	
Arthralgia	v.24.1	
Asthenia	v.24.1	
Back injury	v.24.1	
Back pain	v.24.1	
Bedridden	v.24.1	
Blood creatine phosphokinase increased	v.24.1	
Blood potassium increased	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood pressure systolic increased	v.24.1	
Blood sodium decreased	v.24.1	
Bronchopleural fistula	v.24.1	
Cachexia	v.24.1	
Dizziness	v.24.1	
Drug hypersensitivity	v.24.1	
Dyspnoea	v.24.1	
Erythema	v.24.1	
Fall	v.24.1	
Feeling hot	v.24.1	
Fibromyalgia	v.24.1	
Hand deformity	v.24.1	
Heart rate increased	v.24.1	
Hip fracture	v.24.1	
Hyperkalaemia	v.24.1	
Hypoaesthesia	v.24.1	
Immobile	v.24.1	
Joint swelling	v.24.1	
Muscular weakness	v.24.1	
Musculoskeletal stiffness	v.24.1	
Myalgia	v.24.1	
Osteoporosis	v.24.1	
Oxygen saturation decreased	v.24.1	
Pain	v.24.1	
Pain in extremity	v.24.1	
Pelvic fracture	v.24.1	
Peripheral swelling	v.24.1	
Rales	v.24.1	
Rib fracture	v.24.1	
Road traffic accident	v.24.1	
Vitamin D decreased	v.24.1	
Walking aid user	v.24.1	
Weight decreased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:09:42 AM
Initial Received Date:	2021-09-30 to 2021-12-30
Latest Received Date:	N/A
Total Number of Reports:	197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04955492	1	2021-11-30	2021-12-06	MAH	BL-2021-020127	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
48 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				Product used for unknown indication
SILIQ 2 SINGLE USE PREFILLED SYRINGES	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous	210.0 Milligram	1 every 1 Weeks	15.0 Days	Psoriasis
SILIQ 2 SINGLE USE PREFILLED SYRINGES	Suspect	Solution for injection	Subcutaneous	210.0 Milligram	1 every 2 Weeks		Psoriasis
SILIQ 2 SINGLE USE PREFILLED SYRINGES	Suspect	Solution for injection	Subcutaneous	210.0 Milligram	1 every 2 Weeks		Psoriasis
SILIQ 2 SINGLE USE PREFILLED SYRINGES	Suspect	Solution for injection	Subcutaneous	210.0 Milligram	1 every 2 Weeks	17.0 Days	Psoriasis
VITAMINS NOS	Concomitant						Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Blood pressure increased	v.24.1	16 Days
Inappropriate schedule of product administration	v.24.1	
Musculoskeletal stiffness	v.24.1	
Pain in extremity	v.24.1	
Psoriatic arthropathy	v.24.1	
Treatment noncompliance	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:09:42 AM
Initial Received Date:	2021-09-30 to 2021-12-30
Latest Received Date:	N/A
Total Number of Reports:	197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04955563	0	2021-11-30	2021-11-30	MAH	202101646965	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
62 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total	1.0 Days	COVID-19 immunisation
HUMIRA	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous	40.0 Milligram		337.0 Days	Rheumatoid arthritis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Drug ineffective	v.24.1	
Suspected COVID-19	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04960737	0	2021-12-01	2021-12-01	MAH	202101654991	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
61 Years	Male	172 Centimeter	47 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
REMICADE	Suspect	POWDER FOR SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	750.0 Milligram			Colitis ulcerative

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.24.1	29 Days
Drug ineffective	v.24.1	29 Days
Pain	v.24.1	1 Months
Pyrexia	v.24.1	3 Months
Weight decreased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04961206	0	2021-12-01	2021-12-01	MAH	202101646989	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
55 Years	Female		162 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
REMICADE	Suspect	POWDER FOR SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)				Crohn's disease

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Erythema	v.24.1	
Fluid retention	v.24.1	
Oedema peripheral	v.24.1	
Secretion discharge	v.24.1	
Skin ulcer	v.24.1	
Vaginal haemorrhage	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Weight increased	v.24.1	
Wound infection	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04965656	0	2021-12-02	2021-12-02	MAH	2021TUS075233	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
36 Years	Male		75 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				COVID-19 immunisation
INFLIXIMAB	Concomitant	Powder for injection	Intravenous (not otherwise specified)	5.0 mg/kg			Colitis ulcerative
INFLIXIMAB	Concomitant	NOT SPECIFIED	Intravenous (not otherwise specified)	5.0 mg/kg			Colitis ulcerative
INFLIXIMAB	Concomitant	Powder for injection	Intravenous (not otherwise specified)	500.0 Milligram			Colitis ulcerative
INFLIXIMAB	Concomitant	Powder for injection	Intravenous (not otherwise specified)	5.0 mg/kg			Colitis ulcerative

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MEZAVANT ALSO KNOWN AS MESALAMINE	Suspect	TABLET (DELAYED AND EXTENDED RELEASE)	Unknown				Colitis ulcerative
PREDNISONE	Concomitant	NOT SPECIFIED	Unknown				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Colitis ulcerative	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04967381	0	2021-12-02	2021-12-02	MAH	202101654964	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
30 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Duplicate	E2B_03508779

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETAMINOPHEN	Concomitant	NOT SPECIFIED	Oral	650.0 Milligram		3.0 Days	Premedication
ACYCLOVIR	Concomitant		Oral	200.0 Milligram	2 every 1 Days	33.0 Days	Premedication
ADVAIR	Concomitant	NOT SPECIFIED	Unknown	2.0 Dosage forms	2 every 1 Days		
ALEMTUZUMAB	Suspect	SOLUTION INTRAVENOUS	Intravenous drip	12.0 Milligram	1 every 1 Days	3.0 Days	Relapsing multiple sclerosis
AMOXICILLIN	Suspect	NOT SPECIFIED	Unknown				Cough
CANNABIS SATIVA	Concomitant		Unknown				
CETIRIZINE	Concomitant		Unknown	20.0 Milligram	1 every 1 Days		
CITALOPRAM	Concomitant		Unknown				
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
CYANOCOBALAMIN	Concomitant	NOT SPECIFIED	Unknown				

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
DIPHENHYDRAMINE HYDROCHLORIDE	Concomitant			50.0 Milligram		3.0 Days	Premedication
FLUTICASONE	Concomitant		Unknown	2.0 Dosage forms	2 every 1 Days		
GABAPENTIN	Concomitant	NOT SPECIFIED	Unknown	1500.0 Milligram	1 every 1 Days		
GRAVOL	Concomitant	NOT SPECIFIED	Unknown				Premedication
LAMOTRIGINE	Concomitant	Tablets	Oral				
METHOTREXATE	Suspect		Oral				Sarcoidosis
METHYLPREDNISOLONE	Concomitant		Intravenous (not otherwise specified)	1.0 Gram		3.0 Days	Premedication
MYRBETRIQ	Concomitant	TABLET (EXTENDED-RELEASE)	Unknown				
PANTOPRAZOLE	Concomitant	NOT SPECIFIED	Unknown				
PREDNISONE	Suspect		Oral				Loefgren syndrome, Joint swelling
PREDNISONE	Suspect	NOT SPECIFIED	Unknown				Loefgren syndrome, Joint swelling
RANITIDINE	Concomitant		Oral	150.0 Milligram	2 every 1 Days	3.0 Days	Premedication
TRAZODONE	Concomitant		Oral				
VENTOLIN [SALBUTAMOL]	Concomitant		Unknown				
VITAMIN C [ASCORBIC ACID]	Concomitant		Unknown				
VITAMIN D	Concomitant	NOT SPECIFIED	Unknown		2 every 1 Days		
ZOFRAN [ONDANSETRON]	Concomitant		Oral	4.0 Milligram			Nausea

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal discomfort	v.24.1	
Abdominal pain upper	v.24.1	
Allergy to arthropod bite	v.24.1	
Amnesia	v.24.1	
Anaemia	v.24.1	
Anxiety	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Back pain	v.24.1	
Candida infection	v.24.1	
Cardiac flutter	v.24.1	1 Months
Concussion	v.24.1	
Condition aggravated	v.24.1	
Contusion	v.24.1	
Cough	v.24.1	
Drug hypersensitivity	v.24.1	
Ear infection	v.24.1	
Erythema	v.24.1	
Eye inflammation	v.24.1	
Fall	v.24.1	
Fatigue	v.24.1	
Feeling abnormal	v.24.1	
Headache	v.24.1	
Headache	v.24.1	1 Months
Hypoaesthesia	v.24.1	
Illness	v.24.1	
Immune thrombocytopenia	v.24.1	
Intervertebral disc protrusion	v.24.1	
Joint swelling	v.24.1	
Laboratory test abnormal	v.24.1	
Loefgren syndrome	v.24.1	
Loss of consciousness	v.24.1	
Lymphocyte count decreased	v.24.1	
Malaise	v.24.1	
Middle ear effusion	v.24.1	
Muscle spasms	v.24.1	
Muscular weakness	v.24.1	
Nasopharyngitis	v.24.1	
Nausea	v.24.1	
Nausea	v.24.1	2 Days
Nausea	v.24.1	1 Months
Neck pain	v.24.1	
Nervousness	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Platelet count decreased	v.24.1	
Platelet count increased	v.24.1	
Pneumonia	v.24.1	
Pruritus	v.24.1	
Rash	v.24.1	
Rash macular	v.24.1	
Red blood cells urine positive	v.24.1	
Red cell distribution width increased	v.24.1	
Rhinitis	v.24.1	
Road traffic accident	v.24.1	
Skin discolouration	v.24.1	
Stress	v.24.1	
Synovial cyst	v.24.1	
Urine analysis abnormal	v.24.1	
Urticaria	v.24.1	
Vomiting	v.24.1	1 Days
Vomiting	v.24.1	1 Months
Weight increased	v.24.1	
White blood cell disorder	v.24.1	
White blood cells urine positive	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04968642	0	2021-12-03	2021-12-03	MAH	21K-028-4178168-00	Study	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
67 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect	Injection	Intramuscular			0.0	COVID-19 prophylaxis
COVID-19 VACCINE	Suspect	Injection	Intramuscular			0.0	COVID-19 prophylaxis
COVID-19 VACCINE	Suspect		Intramuscular			0.0	COVID-19 prophylaxis
RINVOQ	Suspect	TABLET (EXTENDED-RELEASE)	Oral	15.0 Milligram	1 every 1 Days		Rheumatoid arthritis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal discomfort	v.24.1	
Back injury	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Contusion	v.24.1	
Diarrhoea	v.24.1	
Fall	v.24.1	
Injury	v.24.1	
Muscle spasms	v.24.1	
Spinal fracture	v.24.1	
Therapeutic product effect incomplete	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04972379	0	2021-12-03	2021-12-03	MAH	202101711703	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
76 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Duplicate	E2B_03159077

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACTEMRA	Suspect	NOT SPECIFIED	Subcutaneous	162.0 Milligram	1 every 1 Weeks	288.0 Days	Rheumatoid arthritis
ACTEMRA	Suspect		Subcutaneous	162.0 Milligram		71.0 Days	Rheumatoid arthritis
BISOPROLOL	Suspect		Unknown				Product used for unknown indication
COVID-19 VACCINE	Suspect		Unknown		Total		COVID-19 immunisation
METHOTREXATE	Suspect		Unknown				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.24.1	
Heart rate irregular	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04972403	0	2021-12-03	2021-12-03	MAH	202101625214	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
65 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total	1.0 Days	COVID-19 immunisation
RINVOQ	Suspect	TABLET (EXTENDED-RELEASE)	Oral	15.0 Milligram	1 every 1 Days	155.0 Days	Rheumatoid arthritis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bacteraemia	v.24.1	1 Months
Endodontic procedure	v.24.1	
Hypoaesthesia	v.24.1	
Hypoaesthesia oral	v.24.1	
Joint dislocation	v.24.1	
Joint noise	v.24.1	
Malaise	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pain	v.24.1	
Pain in jaw	v.24.1	
Post procedural complication	v.24.1	
Retching	v.24.1	
Rheumatoid arthritis	v.24.1	
Vomiting	v.24.1	
White blood cell count abnormal	v.24.1	
Wisdom teeth removal	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04972405	0	2021-12-03	2021-12-03	MAH	202101572097	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
27 Years	Male		69 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown		Total	1.0 Days	COVID-19 immunisation
INFLIXIMAB	Concomitant		Intravenous (not otherwise specified)	600.0 Milligram			Crohn's disease
PREDNISONE	Concomitant	NOT SPECIFIED		1.0 Dosage forms			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Crohn's disease	v.24.1	
Dehydration	v.24.1	
Malaise	v.24.1	
Urticaria	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04972409	0	2021-12-03	2021-12-03	MAH	202101625163	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
65 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
MEPOLIZUMAB	Suspect		Subcutaneous	100.0 Milligram			Asthma

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Inappropriate schedule of product administration	v.24.1	
Product dose omission issue	v.24.1	
Tooth extraction	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04972477	0	2021-12-03	2021-12-03	MAH	202101646975	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
74 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COMIRNATY VIAL CONTAINS 6 DOSES OF 0.3 ML AFTER DILUTION	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular		Total		COVID-19 immunisation
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
MEPOLIZUMAB	Suspect	Solution for injection in pre-filled pen	Subcutaneous	100.0 Milligram			Asthma
MEPOLIZUMAB	Suspect		Subcutaneous	100.0 Milligram			Asthma

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthritis	v.24.1	
Muscular weakness	v.24.1	
Pain in extremity	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Peripheral swelling	v.24.1	
Rheumatoid arthritis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04978266	0	2021-12-06	2021-12-06	MAH	202101638666	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
47 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CELEBREX	Concomitant	Capsules	Unknown	200.0 Milligram	2 every 1 Days		
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
FUROSEMIDE	Concomitant	NOT SPECIFIED	Unknown	40.0 Milligram			
OCRELIZUMAB	Suspect		Unknown	600.0 Milligram			Relapsing-remitting multiple sclerosis
OCRELIZUMAB	Suspect		Unknown	300.0 Milligram			Relapsing-remitting multiple sclerosis
ZOPICLONE	Concomitant	Tablets	Intravenous (not otherwise specified)	50.0 Milligram			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Fatigue	v.24.1	
Hypoaesthesia	v.24.1	
Hypotension	v.24.1	
Infusion related reaction	v.24.1	15 Days
Infusion related reaction	v.24.1	
Pain	v.24.1	
Paraesthesia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04978275	0	2021-12-06	2021-12-06	MAH	202101638639	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
72 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown		Total		COVID-19 immunisation
MEPOLIZUMAB	Suspect		Intravenous (not otherwise specified)	100.0 Milligram			Asthma
MEPOLIZUMAB	Suspect	Powder for injection	Subcutaneous	100.0 Milligram			Asthma
SYNJARDY	Suspect		Unknown		1 every 1 Days		Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood glucose abnormal	v.24.1	
Blood glucose increased	v.24.1	
Cataract	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Diabetic neuropathy	v.24.1	
Glaucoma	v.24.1	
Weight abnormal	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04978281	0	2021-12-06	2021-12-06	MAH	202101638890	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
73 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
MEPOLIZUMAB	Suspect		Subcutaneous	100.0 Milligram			Asthma

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Angiopathy	v.24.1	
Cough	v.24.1	
Dyspnoea	v.24.1	
Fatigue	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04978406	0	2021-12-06	2021-12-06	MAH	202101638937	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
46 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
HUMIRA	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous	40.0 Milligram			Rheumatoid arthritis
HUMIRA	Suspect	Solution for injection	Subcutaneous	40.0 Milligram			Rheumatoid arthritis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Drug resistance	v.24.1	
Illness	v.24.1	
Pyrexia	v.24.1	
Rheumatoid arthritis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04978769	0	2021-12-06	2021-12-06	MAH	202101638554	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
59 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
LIRAGLUTIDE	Suspect		Subcutaneous				Weight control

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Diarrhoea	v.24.1	
Nausea	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04978770	0	2021-12-06	2021-12-06	MAH	202101638709	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
72 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
MEPOLIZUMAB	Suspect	Solution for injection in pre-filled pen	Subcutaneous	100.0 Milligram			Asthma
MEPOLIZUMAB	Suspect	Powder for injection	Subcutaneous	100.0 Milligram			Asthma
MEPOLIZUMAB	Suspect		Intravenous (not otherwise specified)	100.0 Milligram			Asthma

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaemia	v.24.1	
Dyspnoea	v.24.1	
Haemoglobin decreased	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Neoplasm malignant	v.24.1	
Pneumonia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04978774	1	2021-12-06	2021-12-21	MAH	202101638659	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
73 Years	Female	160 Centimeter	90 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AMLODIPINE	Concomitant	Tablets					Hypertension
AMLODIPINE	Concomitant						Hypertension
BECLOMETHASONE	Concomitant						
BECLOMETHASONE	Concomitant						
CALCIUM	Concomitant	NOT SPECIFIED					
CALCIUM	Concomitant						
COVID-19 VACCINE	Suspect		Intramuscular		Total	1.0 Days	COVID-19 immunisation
INS.	Concomitant						
INS.	Concomitant	GLOBULES ORAL					
LIPIDIL EZ	Concomitant	Tablets	Oral	48.0 Milligram	1 every 1 Days		
MESTINON	Concomitant	Tablets					
MESTINON	Concomitant						

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PANTOPRAZOLE	Concomitant	NOT SPECIFIED					
PANTOPRAZOLE	Concomitant						
PRALUENT	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous	75.0 Milligram			Type IIa hyperlipidaemia
TYLENOL	Concomitant						
TYLENOL	Concomitant	NOT SPECIFIED					
VITAMIN D	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Blood glucose increased	v.24.1	
Gait disturbance	v.24.1	
Influenza like illness	v.24.1	
Myasthenia gravis	v.24.1	
Pain	v.24.1	
Rhinorrhoea	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04978777	1	2021-12-06	2021-12-07	MAH	202101638920	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
67 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total	1.0 Days	COVID-19 immunisation
HUMIRA	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous	40.0 Milligram	Cyclical		Colitis ulcerative

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Colitis ulcerative	v.24.1	
Drug level decreased	v.24.1	
Faecal volume decreased	v.24.1	
Haemorrhage	v.24.1	
Therapeutic product effect delayed	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04978778	1	2021-12-06	2021-12-23	MAH	202101638860	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
73 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CARVEDILOL	Concomitant	Tablets	Unknown				
CLOPIDOGREL	Concomitant	Tablets	Unknown				
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
FUROSEMIDE	Concomitant	NOT SPECIFIED	Unknown				
HYDROMORPH CONTIN	Concomitant	CAPSULE, SUSTAINED-RELEASE	Unknown				
IPILIMUMAB	Suspect		Unknown	1.0 mg/kg			Non-small cell lung cancer
NIVOLUMAB	Suspect	SOLUTION INTRAVENOUS	Unknown	360.0 Milligram	1 every 3 Weeks		Non-small cell lung cancer
PANTOPRAZOLE SODIUM	Concomitant		Unknown				
RATIO-ZOPICLONE	Concomitant	Tablets	Unknown				
SYNTHROID	Concomitant	NOT SPECIFIED	Unknown				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Alopecia	v.24.1	
Arthralgia	v.24.1	
Breast pain	v.24.1	
Burning sensation	v.24.1	
Chills	v.24.1	
Constipation	v.24.1	
Diarrhoea	v.24.1	
Diverticulitis	v.24.1	
Dry skin	v.24.1	
Dyspepsia	v.24.1	
Energy increased	v.24.1	
Erythema	v.24.1	
Eye pain	v.24.1	
Fatigue	v.24.1	
Feeling cold	v.24.1	
Flushing	v.24.1	
Galactorrhoea	v.24.1	
Headache	v.24.1	
Hyperhidrosis	v.24.1	
Hypoaesthesia	v.24.1	
Increased appetite	v.24.1	
Myalgia	v.24.1	
Nasopharyngitis	v.24.1	
Night sweats	v.24.1	
Off label use	v.24.1	
Pain in extremity	v.24.1	
Peripheral coldness	v.24.1	
Peripheral swelling	v.24.1	
Photosensitivity reaction	v.24.1	
Pruritus	v.24.1	
Pyrexia	v.24.1	
Rash pruritic	v.24.1	
Tinnitus	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Vomiting	v.24.1	
Weight increased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04978793	0	2021-12-06	2021-12-06	MAH	202101638681	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
71 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACTEMRA	Suspect	Solution for infusion	Intravenous (not otherwise specified)	400.0 Milligram	1 every 1 Months		Rheumatoid arthritis
ACTEMRA	Suspect	NOT SPECIFIED	Intravenous (not otherwise specified)	360.0 Milligram	1 every 1 Months	174.0 Days	Rheumatoid arthritis
ARAVA	Concomitant	Tablets					
ARTHROTEC	Concomitant	Tablets					
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
FOLIC ACID	Concomitant	NOT SPECIFIED					
METHOTREXATE	Concomitant	NOT SPECIFIED	Oral				
PREDNISONE	Concomitant	NOT SPECIFIED					
TYLENOL	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Cough	v.24.1	
Dizziness	v.24.1	
Feeding disorder	v.24.1	
Headache	v.24.1	
Malaise	v.24.1	
Morbid thoughts	v.24.1	
Pyrexia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:09:42 AM
Initial Received Date:	2021-09-30 to 2021-12-30
Latest Received Date:	N/A
Total Number of Reports:	197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04978800	0	2021-12-06	2021-12-06	MAH	202101638725	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
49 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ALEMTUZUMAB	Suspect	SOLUTION INTRAVENOUS	Intravenous drip	12.0 Milligram	1 every 1 Days	3.0 Days	Relapsing-remitting multiple sclerosis
AMLODIPINE BESILATE	Concomitant		Unknown				
BACLOFEN	Concomitant	NOT SPECIFIED	Unknown				
BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE]	Concomitant		Unknown				
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
DEXILANT	Concomitant	CAPSULE, DELAYED RELEASE	Unknown				
FLOVENT	Concomitant	NOT SPECIFIED	Unknown				

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
NASONEX	Concomitant	SPRAY, METERED DOSE	Unknown				
VENTOLIN [SALBUTAMOL]	Concomitant		Unknown				
VITAMIN D	Concomitant	NOT SPECIFIED	Unknown				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
Constipation	v.24.1	
Fatigue	v.24.1	
Headache	v.24.1	
Hyperthyroidism	v.24.1	
Immune system disorder	v.24.1	
Myalgia	v.24.1	
Palpitations	v.24.1	
Stress	v.24.1	
Swelling	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04978806	0	2021-12-06	2021-12-06	MAH	202101638943	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
65 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown		Total		COVID-19 immunisation
ORENCIA	Suspect		Intravenous (not otherwise specified)	1000.0 Milligram	Cyclical		Rheumatoid arthritis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arrhythmia	v.24.1	
Intentional product use issue	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04978809	0	2021-12-06	2021-12-06	MAH	202101638908	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
TYSABRI	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	300.0 Milligram		900.0 Days	Multiple sclerosis
TYSABRI	Suspect		Intravenous (not otherwise specified)	300.0 Milligram		102.0 Days	Multiple sclerosis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Diabetes mellitus	v.24.1	
Prescribed underdose	v.24.1	
Vaccination complication	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04978817	0	2021-12-06	2021-12-06	MAH	202101638877	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
73 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AMITRIPTYLINE	Concomitant		Unknown				
ATORVASTATIN CALCIUM	Concomitant	Tablets	Unknown				
BUDESONIDE;FORMOTEROL FUMARATE	Concomitant		Unknown				
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
DIAMICRON	Concomitant	Tablets	Unknown				
LETROZOLE	Concomitant	Tablets	Unknown				
MEPOLIZUMAB	Suspect		Subcutaneous	100.0 Milligram			Asthma
MEPOLIZUMAB	Suspect		Subcutaneous	100.0 Milligram			Asthma
NASONEX	Concomitant	SPRAY, METERED DOSE	Unknown				
PREDNISONE	Concomitant	NOT SPECIFIED	Unknown				

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PROLIA PRE-FILLED SYRINGE. PRESERVATIVE-FREE.	Concomitant	SOLUTION SUBCUTANEOUS	Unknown				Bone disorder
SALBUTAMOL	Concomitant	NOT SPECIFIED	Unknown				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cataract	v.24.1	
Contusion	v.24.1	
Fall	v.24.1	
Macular hole	v.24.1	
Retinal detachment	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04978937	0	2021-12-06	2021-12-06	MAH	202101638599	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
72 Years	Female		99 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Duplicate	E2B_02839095

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACTEMRA	Suspect	NOT SPECIFIED	Intravenous (not otherwise specified)	720.0 Milligram	1 every 1 Months		Rheumatoid arthritis
ACTEMRA	Suspect	Solution for infusion	Intravenous (not otherwise specified)				Rheumatoid arthritis
ALENDRONATE SODIUM	Suspect		Unknown				Product used for unknown indication
ALPRAZOLAM	Concomitant	Tablets					
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
GLYBURIDE	Concomitant	Tablets					
HYDROXYCHLOROQUINE SULFATE	Concomitant						

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
IBUPROFEN	Concomitant	NOT SPECIFIED					
LIPITOR	Suspect	NOT SPECIFIED	Unknown				Blood cholesterol increased
PAROXETINE	Concomitant	Tablets					
PRAVASTATIN	Suspect		Oral	200.0 Milligram	1 every 1 Days		Product used for unknown indication
SULFASALAZINE	Concomitant	NOT SPECIFIED					
TRIAMCINOLONE ACETONIDE	Concomitant	SUSPENSION INTRA-ARTICULAR	Unknown				
TYLENOL ARTHRITIS PAIN 8H	Concomitant	TABLET (EXTENDED-RELEASE)					Arthritis
XANAX	Concomitant	Tablets					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Agitation	v.24.1	
Arthralgia	v.24.1	
Back pain	v.24.1	
Blood cholesterol increased	v.24.1	
Blood pressure diastolic abnormal	v.24.1	
Blood pressure increased	v.24.1	
Blood pressure systolic abnormal	v.24.1	
Blood pressure systolic increased	v.24.1	
Bone disorder	v.24.1	
Cholelithiasis	v.24.1	
Chromaturia	v.24.1	
Diarrhoea	v.24.1	
Dizziness	v.24.1	
Electrocardiogram abnormal	v.24.1	
Fall	v.24.1	
Fungal infection	v.24.1	
Gastric disorder	v.24.1	
Haemorrhoids	v.24.1	
Headache	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Heart rate decreased	v.24.1	
Heart rate increased	v.24.1	
Hepatic steatosis	v.24.1	
Hyperhidrosis	v.24.1	
Hypotension	v.24.1	
Influenza	v.24.1	
Infusion related reaction	v.24.1	
Joint swelling	v.24.1	
Ligament sprain	v.24.1	
Malaise	v.24.1	
Mobility decreased	v.24.1	
Muscle strain	v.24.1	
Muscular weakness	v.24.1	
Nasal congestion	v.24.1	
Nasopharyngitis	v.24.1	
Osteoporosis	v.24.1	
Oxygen saturation decreased	v.24.1	
Pain	v.24.1	
Pain in extremity	v.24.1	
Peripheral swelling	v.24.1	
Poor dental condition	v.24.1	
Pruritus	v.24.1	
Rash	v.24.1	
Rheumatoid arthritis	v.24.1	
Rib fracture	v.24.1	
Therapeutic product effect decreased	v.24.1	
Tooth disorder	v.24.1	
Vessel puncture site bruise	v.24.1	
Weight decreased	v.24.1	
Weight increased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04983032	0	2021-12-07	2021-12-07	MAH	202101646971	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
67 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown		Total		COVID-19 immunisation
STELARA	Suspect	SOLUTION SUBCUTANEOUS	Intravenous (not otherwise specified)	390.0 Milligram			Crohn's disease
STELARA	Suspect	Solution for injection	Subcutaneous	90.0 Milligram			Crohn's disease

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.24.1	
Crohn's disease	v.24.1	
Epistaxis	v.24.1	
Fatigue	v.24.1	
Feeling abnormal	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.24.1	
Hyperhidrosis	v.24.1	2 Months
Illness	v.24.1	
Infusion related reaction	v.24.1	1 Days
Malaise	v.24.1	
Movement disorder	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04983059	0	2021-12-07	2021-12-07	MAH	202101647016	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
51 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total	1.0 Days	COVID-19 immunisation
HUMIRA	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous	40.0 Milligram			Crohn's disease

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain	v.24.1	
Blister	v.24.1	
Dry skin	v.24.1	
Furuncle	v.24.1	
Haematochezia	v.24.1	
Intentional product misuse	v.24.1	
Rash	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Rash macular	v.24.1	
Skin lesion	v.24.1	
Skin ulcer	v.24.1	
Therapeutic product effect decreased	v.24.1	
Wound complication	v.24.1	
Wound haemorrhage	v.24.1	
Wound secretion	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04983091	1	2021-12-07	2021-12-20	MAH	202101646936	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
89 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
MEPOLIZUMAB	Suspect	Powder for injection	Subcutaneous	100.0 Milligram			Asthma
MEPOLIZUMAB	Suspect	Solution for injection	Subcutaneous	100.0 Milligram			Asthma
MEPOLIZUMAB	Suspect		Subcutaneous	100.0 Milligram			Asthma

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cardiovascular disorder	v.24.1	
Erythema	v.24.1	
Fall	v.24.1	
Herpes zoster	v.24.1	
Hip fracture	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Inappropriate schedule of product administration	v.24.1	
Peripheral swelling	v.24.1	
Product dose omission issue	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04988653	0	2021-12-08	2021-12-08	MAH	202101654954	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
75 Years	Female		65 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACTEMRA	Suspect	NOT SPECIFIED	Intravenous (not otherwise specified)	512.0 Milligram	1 every 1 Months		Rheumatoid arthritis
ACTEMRA	Suspect		Intravenous (not otherwise specified)	220.0 Milligram	1 every 1 Months	105.0 Days	Rheumatoid arthritis
CELEBREX	Concomitant	Capsules					
CITALOPRAM HYDROBROMIDE	Concomitant						
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
ENTOCORT	Concomitant	CAPSULE, SUSTAINED-RELEASE					Colitis
LORAZEPAM	Concomitant	NOT SPECIFIED	Unknown				

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PREDNISONE	Concomitant	NOT SPECIFIED	Subcutaneous				
ROSUVASTATIN	Concomitant	NOT SPECIFIED	Subcutaneous				
SULFASALAZINE	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Blood cholesterol increased	v.24.1	
Blood pressure diastolic abnormal	v.24.1	
Blood pressure fluctuation	v.24.1	
Blood pressure systolic abnormal	v.24.1	
Blood pressure systolic increased	v.24.1	
Blood thyroid stimulating hormone increased	v.24.1	
Colitis	v.24.1	
Contusion	v.24.1	
Dental caries	v.24.1	
Diarrhoea	v.24.1	
Disability assessment scale score increased	v.24.1	
Dizziness	v.24.1	
Drug ineffective	v.24.1	
Fall	v.24.1	
Fatigue	v.24.1	
Headache	v.24.1	
Hyperhidrosis	v.24.1	
Hypoaesthesia	v.24.1	
Hypotension	v.24.1	
Inflammation	v.24.1	
Joint swelling	v.24.1	
Loose tooth	v.24.1	
Malaise	v.24.1	
Mean cell haemoglobin concentration increased	v.24.1	
Mean cell volume increased	v.24.1	
Migraine	v.24.1	
Muscle strain	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Musculoskeletal stiffness	v.24.1	
Nasal ulcer	v.24.1	17 Days
Nasopharyngitis	v.24.1	17 Days
Nasopharyngitis	v.24.1	
Nausea	v.24.1	
Oropharyngeal pain	v.24.1	
Oropharyngeal pain	v.24.1	
Oxygen saturation decreased	v.24.1	
Pain	v.24.1	1 Days
Pain in extremity	v.24.1	
Paraesthesia	v.24.1	
Pelvic fracture	v.24.1	
Peripheral swelling	v.24.1	
Pneumonia	v.24.1	
Productive cough	v.24.1	
Rhinorrhoea	v.24.1	
Seasonal allergy	v.24.1	
Sinus congestion	v.24.1	
Sinusitis	v.24.1	
Skin ulcer	v.24.1	17 Days
Therapeutic response decreased	v.24.1	
Toothache	v.24.1	
Upper limb fracture	v.24.1	
Weight decreased	v.24.1	
Weight increased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04988999	0	2021-12-08	2021-12-08	MAH	202101654938	Spontaneous	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown		Total		COVID-19 immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Back pain	v.24.1	
Herpes zoster	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
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Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04996462	0	2021-12-10	2021-12-10	MAH	CA2021234935	Study	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
80 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	
Linked	
Linked	
Linked	
Linked	E2B_03528104
Linked	E2B_01951835

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ADVAIR	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication
COVID-19 VACCINE	Suspect		Unknown				Product used for unknown indication
MEPOLIZUMAB	Suspect		Subcutaneous	100.0 Milligram			Asthma

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MONTELUKAST	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication
PREDNISONE	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication
SALBUTAMOL	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dyspnoea	v.24.1	
Hospitalisation	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
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Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_04997971	0	2021-12-10	2021-12-10	MAH	2021TUS037401	Study	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
53 Years	Female		59 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CAFFEINE	Concomitant	NOT SPECIFIED	Unknown	8.0 Milligram			
CETIRIZINE HYDROCHLORIDE	Concomitant		Unknown	20.0 Milligram	1 every 1 Days		
CODEINE	Concomitant	NOT SPECIFIED	Unknown	5.0 ml			
COVID-19 VACCINE	Suspect		Unknown				COVID-19 immunisation
CYANOCOBALAMIN ZINC TANNATE	Concomitant						Product used for unknown indication
CYANOCOBALAMIN ZINC TANNATE	Concomitant		Unknown		1 every 2 Weeks		Product used for unknown indication
FENTANYL	Concomitant	NOT SPECIFIED	Unknown	26.0 Milligram	1 every 1 Weeks		

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
FENTANYL	Concomitant	PATCH	Unknown	25.0 Microgram	every 72 Hours		
INNOHEP	Concomitant	LIQUID SUBCUTANEOUS	Unknown	12000.0 IU (International Unit)	1 every 1 Days		
INNOHEP	Concomitant			12000.0 IU (International Unit)	1 every 1 Days		
NORMAL SALINE	Concomitant	NOT SPECIFIED	Unknown	1500.0 ml	3 every 1 Weeks		
NORMAL SALINE	Concomitant		Unknown	1800.0 ml	3 every 1 Weeks		
OSTOMED	Concomitant		Unknown				
PANTOPRAZOLE SODIUM	Concomitant		Unknown	40.0 Milligram	2 every 1 Days		
TEDUGLUTIDE	Suspect		Unknown	1.5 Milligram	1 every 1 Days		Short-bowel syndrome
TYLENOL	Concomitant	NOT SPECIFIED	Unknown	160.0 Milligram			
VITAMIN A	Concomitant	NOT SPECIFIED	Unknown		1 every 1 Days		
VITAMIN D	Concomitant	Capsules	Unknown		2 every 1 Weeks		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain	v.24.1	
Abdominal pain lower	v.24.1	
Abnormal faeces	v.24.1	
Anxiety	v.24.1	
Back pain	v.24.1	
Cholelithiasis	v.24.1	
Diarrhoea	v.24.1	
Discomfort	v.24.1	
Dyspnoea	v.24.1	
Eructation	v.24.1	
Fatigue	v.24.1	
Feeling abnormal	v.24.1	
Gastrointestinal sounds abnormal	v.24.1	
Gastrointestinal stoma output increased	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Injection site pain	v.24.1	
Nasal discomfort	v.24.1	
Nausea	v.24.1	
Oedema	v.24.1	
Pain	v.24.1	
Pallor	v.24.1	
Pancreatic disorder	v.24.1	
Peripheral swelling	v.24.1	
Renal neoplasm	v.24.1	
Skin warm	v.24.1	
Sleep disorder	v.24.1	
Thirst	v.24.1	
Vomiting	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_05011774	1	2021-12-14	2021-12-17	MAH	20211214858	Study	Pharmacist

Serious report?	Death:	Yes	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
69 Years	Female			Fatal

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				COVID-19 prophylaxis
STELARA	Suspect	SOLUTION SUBCUTANEOUS	Intravenous (not otherwise specified)	520.0 Milligram	1 every 8 Weeks		Crohn's disease

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cholelithiasis	v.24.1	
Crohn's disease	v.24.1	
Death	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_05016466	0	2021-12-15	2021-12-15	MAH	21K-028-4046990-00	Study	Consumer/other non health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
36 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular			0.0	COVID-19 immunisation
COVID-19 VACCINE	Suspect		Intramuscular			0.0	COVID-19 immunisation
HUMIRA	Suspect	Solution for injection in pre-filled pen	Subcutaneous	40.0 Milligram	1 every 1 Weeks		Crohn's disease
HUMIRA	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous	40.0 Milligram	1 every 2 Weeks	5.0 Years	Crohn's disease

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Crohn's disease	v.24.1	-212
Drug ineffective	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Injection site rash	v.24.1	
Obstruction	v.24.1	
Pain in extremity	v.24.1	
Psoriasis	v.24.1	
Rash	v.24.1	
Scar	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_05028497	0	2021-12-17	2021-12-17	MAH	202101746598	Study	

Serious report?	Death:	Disability:	Congenital Anomaly:
Serious	Yes	No	No
	Life Threatening:	**Hospitalization:**	**Other Medically Important Conditions:**
	No	Yes	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
70 Years	Male	159 Centimeter	63 Kilogram	Fatal

Link / Duplicate Report Information

Record Type	Link AER** Number
Duplicate	E2B_04997896

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
LONSURF	Suspect	Tablets	Oral				Colorectal cancer metastatic

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pneumonia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_05035425	0	2021-12-20	2021-12-20	MAH	20211035108	Study	Consumer/other non health professional

Serious report?
Serious

Death:	No	**Disability:**	No	**Congenital Anomaly:**	No
Life Threatening:	No	**Hospitalization:**	Yes	**Other Medically Important Conditions:**	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
62 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	
Linked	E2B_01425729
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				COVID-19 prophylaxis
REMICADE	Suspect	POWDER FOR SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	900.0 Milligram	1 every 6 Weeks		Colitis ulcerative

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.24.1	
COVID-19	v.24.1	-265

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Colitis ulcerative	v.24.1	
Gait disturbance	v.24.1	
Hyperhidrosis	v.24.1	
Pneumonia	v.24.1	
Tremor	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_05036942	0	2021-12-20	2021-12-20	MAH	202101730354	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
84 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown		Total		COVID-19 immunisation
REMICADE	Suspect	POWDER FOR SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)				Rheumatoid arthritis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cellulitis	v.24.1	1 Months

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_05036944	0	2021-12-20	2021-12-20	MAH	202101730418	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
19 Years	Male		80 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
FOLIC ACID	Concomitant	NOT SPECIFIED	Unknown				
METHOTREXATE	Concomitant	NOT SPECIFIED	Unknown	10.0 Milligram	1 every 1 Weeks		
REMICADE	Suspect	POWDER FOR SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	800.0 Milligram			Crohn's disease

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Respiratory tract infection	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_05036951	0	2021-12-20	2021-12-20	MAH	2021448676	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
83 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ALENDRONATE SODIUM	Concomitant						
ALLOPURINOL	Concomitant	Tablets					
BUDESONIDE/FORMOTEROL FUMARATE	Concomitant						
COVID-19 VACCINE	Suspect		Unknown			1.0 Days	COVID-19 immunisation
DILTIAZEM	Concomitant						Blood pressure measurement
INFLUENZA VACCINES	Concomitant					1.0 Days	Influenza immunisation
MYCOPHENOLIC ACID	Concomitant	NOT SPECIFIED					
PANTOPRAZOLE	Concomitant	NOT SPECIFIED					

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
RUXIENCE CONCENTRATE. SINGLE USE VIAL	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	500.0 Milligram			Rheumatoid arthritis
SALBUTAMOL	Concomitant	NOT SPECIFIED					
SPIRONOLACTONE	Concomitant						
SULFASALAZINE	Concomitant	NOT SPECIFIED		1.0 Dosage forms			
WARFARIN	Concomitant						
ZOPICLONE	Concomitant	Tablets					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.24.1	
Fall	v.24.1	
Intentional product use issue	v.24.1	
Joint injury	v.24.1	
Off label use	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_05036956	0	2021-12-20	2021-12-20	MAH	202101730235	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
66 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
MEPOLIZUMAB	Suspect		Subcutaneous	100.0 Milligram			Asthma

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Colitis	v.24.1	
Cystitis	v.24.1	
Nephrolithiasis	v.24.1	
Urticaria	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_05036958	0	2021-12-20	2021-12-20	MAH	202101729973	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
59 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACTEMRA	Suspect		Subcutaneous	162.0 Milligram	Cyclical		Rheumatoid arthritis
ACTEMRA	Suspect	NOT SPECIFIED	Subcutaneous	162.0 Milligram	Cyclical	365.0 Days	Rheumatoid arthritis
ARAVA	Concomitant	Tablets					
COLACE	Concomitant	NOT SPECIFIED					
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
IRON	Concomitant						
NAPROXEN	Concomitant	NOT SPECIFIED	Unknown				
PANTOPRAZOLE	Concomitant	NOT SPECIFIED					
PREDNISONE	Concomitant	NOT SPECIFIED					
TYLENOL ARTHRITIS PAIN 8H	Concomitant	TABLET (EXTENDED-RELEASE)					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Joint swelling	v.24.1	1 Days
Mean cell haemoglobin decreased	v.24.1	
Mean cell volume decreased	v.24.1	
Renal impairment	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_05036960	0	2021-12-20	2021-12-20	MAH	202101730289	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
51 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
REMICADE	Suspect	POWDER FOR SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	450.0 Milligram			Colitis ulcerative

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anal abscess	v.24.1	
Diarrhoea	v.24.1	
Frequent bowel movements	v.24.1	
General physical health deterioration	v.24.1	
Haematochezia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_05036961	0	2021-12-20	2021-12-20	MAH	202101729915	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
73 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
MEPOLIZUMAB	Suspect		Subcutaneous	100.0 Milligram			Asthma

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Epistaxis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_05036962	0	2021-12-20	2021-12-20	MAH	202101730118	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
REMICADE	Suspect	POWDER FOR SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)				Colitis ulcerative

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthritis infective	v.24.1	
Fatigue	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_05036986	0	2021-12-20	2021-12-20	MAH	202101729854	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
54 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
HUMIRA	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous	40.0 Milligram		1460.0 Days	Ankylosing spondylitis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cystitis escherichia	v.24.1	
Dizziness	v.24.1	
Illness	v.24.1	
Oedematous kidney	v.24.1	
Renal abscess	v.24.1	
Renal disorder	v.24.1	
Vertigo	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Vomiting	v.24.1	
Weight decreased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_05037008	0	2021-12-20	2021-12-20	MAH	202101730178	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
67 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ADVAIR	Concomitant	NOT SPECIFIED	Unknown	1.0 Dosage forms	2 every 1 Days		
AZITHROMYCIN	Concomitant	NOT SPECIFIED	Unknown				
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
MEPOLIZUMAB	Suspect		Subcutaneous	100.0 Milligram			Asthma
VENTOLIN [SALBUTAMOL]	Concomitant		Unknown				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.24.1	2 Days
Pneumonia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_05042352	0	2021-12-21	2021-12-21	MAH	202101747679	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
46 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
MEPOLIZUMAB	Suspect		Subcutaneous	100.0 Milligram			Asthma

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthma	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Product dose omission issue	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_05042357	0	2021-12-21	2021-12-21	MAH	202101748042	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
65 Years	Male		79 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
STELARA	Suspect	Solution for injection	Unknown	90.0 Milligram			Crohn's disease
STELARA	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous	90.0 Milligram	1 every 1 Months		Crohn's disease

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.24.1	
Crohn's disease	v.24.1	
Drug ineffective	v.24.1	
Product use issue	v.24.1	
Salmonellosis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_05042365	0	2021-12-21	2021-12-21	MAH	202101738938	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
29 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CETIRIZINE HYDROCHLORIDE	Suspect		Unknown		1 every 1 Days		Product used for unknown indication
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
MEPOLIZUMAB	Suspect		Subcutaneous	100.0 Milligram			Asthma
MEPOLIZUMAB	Suspect		Subcutaneous	100.0 Milligram			Asthma

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain	v.24.1	
Arrhythmia	v.24.1	
Breath sounds abnormal	v.24.1	
Depression	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Discomfort	v.24.1	
Dry eye	v.24.1	
Dry skin	v.24.1	
Eye pruritus	v.24.1	
Fatigue	v.24.1	
Hypersensitivity	v.24.1	
Injection site pain	v.24.1	
Insomnia	v.24.1	
Lacrimation increased	v.24.1	
Muscular weakness	v.24.1	
Nasal congestion	v.24.1	
Nephrolithiasis	v.24.1	
Ocular hyperaemia	v.24.1	
Oropharyngeal pain	v.24.1	
Pyrexia	v.24.1	
Rash	v.24.1	
Rash erythematous	v.24.1	
Seasonal allergy	v.24.1	
Sinus congestion	v.24.1	
Skin irritation	v.24.1	
Sleep apnoea syndrome	v.24.1	
Sleep disorder	v.24.1	
Weight decreased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_05042371	0	2021-12-21	2021-12-21	MAH	202101738928	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
58 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
ELTROXIN	Concomitant	Tablets					
FLUOXETINE	Concomitant	NOT SPECIFIED	Unknown	20.0 Milligram			
MORPHINE SULFATE	Concomitant	NOT SPECIFIED	Unknown	10.0 Milligram	6 every 1 Days		
MRNA-1273 SARS-COV-2	Suspect	NOT SPECIFIED	Unknown				Product used for unknown indication
OCRELIZUMAB	Suspect		Intravenous (not otherwise specified)	300.0 Milligram			Relapsing-remitting multiple sclerosis
RISPERIDONE	Concomitant	NOT SPECIFIED	Unknown	0.5 Milligram			
SENNA	Concomitant						
VALPROATE SEMISODIUM	Concomitant	NOT SPECIFIED	Unknown	500.0 Milligram			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anticipatory anxiety	v.24.1	
Anxiety	v.24.1	
Asthenia	v.24.1	
Fatigue	v.24.1	
Malaise	v.24.1	
Multiple sclerosis relapse	v.24.1	
Nasopharyngitis	v.24.1	
Nausea	v.24.1	
Pain in extremity	v.24.1	
Pyrexia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_05042373	0	2021-12-21	2021-12-21	MAH	202101746985	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
79 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
MEPOLIZUMAB	Suspect		Subcutaneous	100.0 Milligram			Asthma

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fall	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Sleep terror	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_05042379	0	2021-12-21	2021-12-21	MAH	202101747491	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
59 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
SIMPONI	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous	50.0 Milligram	1 every 1 Months	342.0 Days	Rheumatoid arthritis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Drug ineffective	v.24.1	
Injection site pain	v.24.1	
Rheumatoid arthritis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_05042384	0	2021-12-21	2021-12-21	MAH	202101746860	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
86 Years	Female		45 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACTEMRA	Suspect	NOT SPECIFIED	Subcutaneous	162.0 Milligram			Rheumatoid arthritis
CALCIUM	Concomitant	NOT SPECIFIED					
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
FLOVENT	Concomitant	NOT SPECIFIED					
HYALURONIC ACID CAPSULES	Concomitant	Capsule					
PULMICORT	Concomitant	NOT SPECIFIED					
RAMIPRIL	Concomitant	NOT SPECIFIED	Unknown		1 every 1 Days		
SYNTHROID	Concomitant	NOT SPECIFIED					
VITAMIN D3	Concomitant	Capsules					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Affective disorder	v.24.1	
Arthralgia	v.24.1	
Asthenia	v.24.1	
C-reactive protein increased	v.24.1	
Cerebrovascular accident	v.24.1	
Chondromalacia	v.24.1	
Drug ineffective	v.24.1	
Eye infection	v.24.1	
Fatigue	v.24.1	
Finger deformity	v.24.1	
Hand deformity	v.24.1	
Laryngitis	v.24.1	
Lower respiratory tract congestion	v.24.1	
Movement disorder	v.24.1	
Nasopharyngitis	v.24.1	
Osteoarthritis	v.24.1	
Periorbital infection	v.24.1	
Sinusitis	v.24.1	
Transient ischaemic attack	v.24.1	
Upper respiratory tract infection	v.24.1	
Urinary tract infection	v.24.1	
Weight increased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_05042387	0	2021-12-21	2021-12-21	MAH	202101739599	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
62 Years	Female		86 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown		Total	1.0 Days	COVID-19 immunisation
STELARA	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous	90.0 Milligram	Cyclical		Colitis ulcerative

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cellulitis	v.24.1	7 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_05042396	0	2021-12-21	2021-12-21	MAH	202101739587	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
46 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASA	Concomitant	NOT SPECIFIED	Oral	80.0 Milligram	1 every 1 Days		Asthma
AZITHROMYCIN	Concomitant	NOT SPECIFIED	Oral	250.0 Milligram	1 every 1 Days		Infection prophylaxis
BISOPROLOL	Concomitant		Oral	5.0 Milligram	1 every 1 Days		
CALCIUM	Concomitant	NOT SPECIFIED	Unknown				
CLOPIDOGREL	Suspect	Tablets	Oral	75.0 Milligram	1 every 1 Days	20.0 Days	Product used for unknown indication
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
FUROSEMIDE	Concomitant	NOT SPECIFIED	Oral	20.0 Milligram	2 every 1 Days		
MEPOLIZUMAB	Suspect		Subcutaneous	100.0 Milligram			Asthma
MOMETASONE	Concomitant		Unknown				
MONTELUKAST SODIUM	Concomitant		Unknown				

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
OMEGA 3 [FISH OIL]	Concomitant		Unknown				
PANTOPRAZOLE	Concomitant	NOT SPECIFIED	Unknown				
PREGABALIN	Concomitant	Capsules	Unknown				
SPIRONOLACTONE	Concomitant	Tablets	Oral	25.0 Milligram	1 every 1 Days		
VALACYCLOVIR HYDROCHLORIDE	Concomitant		Unknown				
VENTOLIN [SALBUTAMOL]	Concomitant		Unknown				
VITAMIN C [ASCORBIC ACID]	Concomitant		Unknown				
ZENHALE	Concomitant	AEROSOL, METERED DOSE	Unknown				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cerebrovascular accident	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_05042399	0	2021-12-21	2021-12-21	MAH	202101739581	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
87 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
MEPOLIZUMAB	Suspect		Subcutaneous	100.0 Milligram			Asthma

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Myocardial infarction	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:09:42 AM
Initial Received Date:	2021-09-30 to 2021-12-30
Latest Received Date:	N/A
Total Number of Reports:	197 Report(s)

Report Information

***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_05042403	1	2021-12-21	2021-12-22	MAH	202101747639	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
63 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
RINVOQ	Suspect	TABLET (EXTENDED-RELEASE)	Oral	15.0 Milligram	1 every 1 Days		Rheumatoid arthritis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Rheumatoid arthritis	v.24.1	
Therapeutic product effect decreased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_05042408	0	2021-12-21	2021-12-21	MAH	202101738917	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
51 Years	Male		62 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACTEMRA	Suspect	NOT SPECIFIED	Intravenous (not otherwise specified)				Rheumatoid arthritis
ACTEMRA	Suspect		Intravenous (not otherwise specified)	480.0 Milligram	1 every 1 Months		Rheumatoid arthritis
ARAVA	Suspect	Tablets	Unknown				Product used for unknown indication
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
OLMETEC	Concomitant	Tablets					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain	v.24.1	
Abdominal pain upper	v.24.1	
Acne	v.24.1	
Arthralgia	v.24.1	
Arthropod sting	v.24.1	
Back pain	v.24.1	
Blister	v.24.1	
Blood pressure diastolic abnormal	v.24.1	
Blood pressure diastolic increased	v.24.1	
Blood pressure fluctuation	v.24.1	
Blood pressure increased	v.24.1	
Blood pressure systolic abnormal	v.24.1	
Blood pressure systolic increased	v.24.1	
Cough	v.24.1	
Dyspnoea exertional	v.24.1	
Genital rash	v.24.1	
Heart rate decreased	v.24.1	
Hypotension	v.24.1	1 Days
Infected cyst	v.24.1	15 Days
Infection	v.24.1	
Influenza	v.24.1	
Infusion related reaction	v.24.1	
Investigation abnormal	v.24.1	
Joint swelling	v.24.1	
Limb injury	v.24.1	
Lymphadenopathy	v.24.1	
Malaise	v.24.1	
Mass	v.24.1	
Nasopharyngitis	v.24.1	
Oxygen saturation decreased	v.24.1	
Pain	v.24.1	
Peripheral swelling	v.24.1	
Pollakiuria	v.24.1	
Rash	v.24.1	1 Years
Rash	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Rheumatoid arthritis	v.24.1	
Skin disorder	v.24.1	
Skin ulcer	v.24.1	
Stress	v.24.1	
Swelling	v.24.1	
Tooth abscess	v.24.1	
Tooth infection	v.24.1	
Weight decreased	v.24.1	
Weight increased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_05042412	0	2021-12-21	2021-12-21	MAH	202101747341	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
18 Years	Male		149 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
REMICADE	Suspect	POWDER FOR SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	600.0 Milligram			Crohn's disease

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.24.1	
Incorrect dose administered	v.24.1	
Off label use	v.24.1	
Pneumonia	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_05042420	0	2021-12-21	2021-12-21	MAH	202101748148	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
69 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
HUMIRA	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous	40.0 Milligram		113.0 Days	Rheumatoid arthritis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Aphthous ulcer	v.24.1	
Blood sodium decreased	v.24.1	
Fatigue	v.24.1	
Haemoglobin decreased	v.24.1	
Haemorrhage	v.24.1	
Hypophagia	v.24.1	
Malaise	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Oropharyngeal pain	v.24.1	
Pneumonia	v.24.1	
Somnolence	v.24.1	
Vaccination complication	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_05043174	0	2021-12-21	2021-12-21	MAH	202101739523	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
39 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ATIVAN	Concomitant	NOT SPECIFIED					
CITALOPRAM	Concomitant						
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
PREDNISONE	Concomitant	NOT SPECIFIED					
RIZATRIPTAN	Concomitant	NOT SPECIFIED					
VEDOLIZUMAB	Suspect		Intravenous (not otherwise specified)	300.0 Milligram			Colitis ulcerative

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain	v.24.1	
Abdominal pain upper	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood pressure decreased	v.24.1	
Diarrhoea	v.24.1	
Drug ineffective	v.24.1	
Haematochezia	v.24.1	
Heart rate increased	v.24.1	
Hyperhidrosis	v.24.1	
Malaise	v.24.1	
Nausea	v.24.1	
Off label use	v.24.1	
Pallor	v.24.1	
Pyrexia	v.24.1	
Vaccination complication	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_05043181	0	2021-12-21	2021-12-21	MAH	202101748284	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
49 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETAMINOPHEN	Concomitant	NOT SPECIFIED	Intravenous drip			11.0 Days	Premedication
ACYCLOVIR	Concomitant		Oral	200.0 Milligram		11.0 Days	Premedication
ALEMTUZUMAB	Suspect		Intravenous drip	12.0 Milligram	1 every 1 Days	3.0 Days	Relapsing-remitting multiple sclerosis
ALEMTUZUMAB	Suspect	SOLUTION INTRAVENOUS	Intravenous drip	12.0 Milligram	1 every 1 Days	2.0 Days	Relapsing-remitting multiple sclerosis
BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE]	Concomitant		Oral	50.0 Milligram		11.0 Days	Premedication
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
FROVATRIPTAN	Concomitant		Oral	2.5 Milligram			

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
GABAPENTIN	Concomitant	NOT SPECIFIED	Unknown				
GABAPENTIN	Concomitant		Oral	300.0 Milligram			
GRAVOL	Concomitant	NOT SPECIFIED	Oral	50.0 Milligram		11.0 Days	Premedication
METHYLPREDNISOLONE	Concomitant		Intravenous (not otherwise specified)	1.0 Gram		11.0 Days	Premedication
MIRTAZAPINE	Concomitant	Tablets	Oral	45.0 Milligram			
NAPROXEN	Concomitant	NOT SPECIFIED	Oral	500.0 Milligram			
NORTRIPTYLINE	Concomitant	Capsules	Oral	25.0 Milligram			
RANITIDINE	Concomitant		Oral	150.0 Milligram		11.0 Days	Premedication
VENLAFAXINE	Concomitant		Oral	37.5 Milligram			
VITAMIN B 12 [VITAMIN B12 NOS]	Concomitant		Unknown				
VITAMIN D [COLECALCIFEROL]	Concomitant		Unknown				
VITAMIN E NOS	Concomitant		Unknown				
ZOLMITRIPTAN	Concomitant	NOT SPECIFIED	Oral	5.0 Milligram			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain upper	v.24.1	
Atypical pneumonia	v.24.1	
Blood pressure increased	v.24.1	
Chest pain	v.24.1	
Cough	v.24.1	
Decreased appetite	v.24.1	
Diarrhoea	v.24.1	
Gait disturbance	v.24.1	
Haemophagocytic lymphohistiocytosis	v.24.1	
Headache	v.24.1	
Heart rate increased	v.24.1	
Hyperhidrosis	v.24.1	
Influenza	v.24.1	
Infusion site pain	v.24.1	
Malaise	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Migraine	v.24.1	
Nasopharyngitis	v.24.1	
Nausea	v.24.1	
Oral herpes	v.24.1	
Oropharyngeal pain	v.24.1	
Pain in extremity	v.24.1	
Paraesthesia	v.24.1	
Sinusitis	v.24.1	
Vertigo	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_05043214	0	2021-12-21	2021-12-21	MAH	202101748061	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
45 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
HUMIRA	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous	40.0 Milligram			Rheumatoid arthritis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Drug interaction	v.24.1	
Hypersensitivity	v.24.1	
Malaise	v.24.1	
Myocardial infarction	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:09:42 AM
Initial Received Date:	2021-09-30 to 2021-12-30
Latest Received Date:	N/A
Total Number of Reports:	197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_05048125	0	2021-12-22	2021-12-22	MAH	20211233221	Study	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
57 Years	Female		52 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				COVID-19 prophylaxis
FOLIC ACID	Concomitant		Unknown				Product used for unknown indication
METHOTREXATE	Concomitant	NOT SPECIFIED	Oral	12.5 Milligram	1 every 1 Weeks		Product used for unknown indication
REMICADE	Suspect	POWDER FOR SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	300.0 Milligram	1 every 8 Weeks		Crohn's disease

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cellulitis	v.24.1	-304
Decreased appetite	v.24.1	
Diarrhoea	v.24.1	
Fatigue	v.24.1	
Headache	v.24.1	
Infrequent bowel movements	v.24.1	
Phlebitis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:09:42 AM
Initial Received Date:	2021-09-30 to 2021-12-30
Latest Received Date:	N/A
Total Number of Reports:	197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_05048990	0	2021-12-22	2021-12-22	MAH	202101766871	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
24 Years	Female		77 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACTEMRA	Suspect	NOT SPECIFIED	Intravenous (not otherwise specified)	430.0 Milligram	1 every 1 Months		Rheumatoid arthritis
ACTEMRA	Suspect	Solution for infusion	Intravenous (not otherwise specified)	480.0 Milligram	1 every 1 Months		Rheumatoid arthritis
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
HYDROXYCHLOROQUINE SULFATE	Concomitant						
MOVISSE	Concomitant	Tablets					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anxiety	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Cough	v.24.1	
Depression	v.24.1	
Inflammation	v.24.1	
Influenza	v.24.1	
Nasopharyngitis	v.24.1	
Pain	v.24.1	
Rheumatoid arthritis	v.24.1	
Weight increased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:09:42 AM
Initial Received Date:	2021-09-30 to 2021-12-30
Latest Received Date:	N/A
Total Number of Reports:	197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_05049004	0	2021-12-22	2021-12-22	MAH	202101767551	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
29 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
HUMIRA	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous	40.0 Milligram	Cyclical		Rheumatoid arthritis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Drug ineffective	v.24.1	
Rheumatoid arthritis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_05049007	0	2021-12-22	2021-12-22	MAH	202101767234	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
31 Years	Female		99 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Duplicate	E2B_05017787

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETYLSALICYLIC ACID	Concomitant	NOT SPECIFIED	Oral	81.0 Milligram			
ACETYLSALICYLIC ACID	Concomitant		Unknown				
AGALSIDASE ALFA	Suspect		Unknown	6.0 Dosage forms			Fabry's disease
AGALSIDASE ALFA	Suspect		Unknown	19.36 Milligram			Fabry's disease
CALCIUM/MAGNESIUM	Concomitant						
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
DICLECTIN	Concomitant	TABLET (DELAYED-RELEASE)	Unknown	10.0 Milligram			
DOXYLAMINE	Concomitant		Unknown				
ERGOCALCIFEROL	Concomitant	NOT SPECIFIED	Unknown				
IMODIUM	Concomitant	NOT SPECIFIED	Unknown				
LIOTHYRONINE SODIUM	Concomitant		Unknown				

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MAGNESIUM PIDOLATE	Concomitant						
MIRENA	Concomitant	INSERT (EXTENDED-RELEASE)	Unknown				
TYLENOL	Concomitant	NOT SPECIFIED	Unknown				
ZANTAC	Concomitant	NOT SPECIFIED	Unknown				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood pressure decreased	v.24.1	
Body temperature increased	v.24.1	
Cholestasis of pregnancy	v.24.1	
Exposure during pregnancy	v.24.1	
Fatigue	v.24.1	
Heart rate increased	v.24.1	
Hypoacusis	v.24.1	
Illness	v.24.1	
Increased appetite	v.24.1	
Malaise	v.24.1	
Morning sickness	v.24.1	
Muscle spasms	v.24.1	
Nausea	v.24.1	
Pre-eclampsia	v.24.1	
Protein urine present	v.24.1	
Pruritus	v.24.1	
Vomiting	v.24.1	
Weight decreased	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_05049008	0	2021-12-22	2021-12-22	MAH	202101758887	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
57 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACTEMRA	Suspect		Intravenous (not otherwise specified)	680.0 Milligram			Rheumatoid arthritis
ACTEMRA	Suspect	Solution for injection in pre-filled syringe	Subcutaneous	162.0 Milligram			Rheumatoid arthritis
ACTEMRA	Suspect	NOT SPECIFIED	Intravenous (not otherwise specified)	640.0 Milligram			Rheumatoid arthritis
ALENDRONATE SODIUM	Concomitant						
AMLODIPINE BESILATE	Concomitant						
CLONAZEPAM	Concomitant	Tablets					
COUMADIN	Concomitant	Tablets					
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CYCLOBENZAPRINE HYDROCHLORIDE	Concomitant						
ERDOSTEINE	Concomitant						
NAPROXEN	Concomitant	NOT SPECIFIED	Unknown				
OMEPRAZOLE	Concomitant	NOT SPECIFIED					
PERINDOPRIL	Concomitant						
PREDNISONE	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.24.1	
Back pain	v.24.1	
Depressive symptom	v.24.1	
Food allergy	v.24.1	
Headache	v.24.1	
Iodine allergy	v.24.1	
Musculoskeletal stiffness	v.24.1	
Nodule	v.24.1	
Oedema peripheral	v.24.1	
Oral disorder	v.24.1	
Pruritus	v.24.1	
Seasonal allergy	v.24.1	
Sensory disturbance	v.24.1	
Synovitis	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_05049032	0	2021-12-22	2021-12-22	MAH	202101767111	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
TYSABRI	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	300.0 Milligram	1 every 1 Months		Relapsing multiple sclerosis
TYSABRI	Suspect	Solution for infusion	Intramuscular	300.0 Milligram	1 every 1 Months		Relapsing multiple sclerosis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Crohn's disease	v.24.1	
Diarrhoea	v.24.1	
Multiple sclerosis relapse	v.24.1	
Vaccination complication	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_05049574	0	2021-12-22	2021-12-22	MAH	202101767508	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
40 Years	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total	31.0 Days	COVID-19 immunisation
HUMIRA	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous	40.0 Milligram			Rheumatoid arthritis
HUMIRA	Suspect	Solution for injection	Subcutaneous	40.0 Milligram			Rheumatoid arthritis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Drug ineffective	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Nail bed infection	v.24.1	
Oedema peripheral	v.24.1	
Rheumatoid arthritis	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Suspected COVID-19	v.24.1	
Vaccination site erythema	v.24.1	
Vaccination site pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_05049616	0	2021-12-22	2021-12-22	MAH	202101766985	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
73 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
MEPOLIZUMAB	Suspect		Subcutaneous	100.0 Milligram			Asthma
MEPOLIZUMAB	Suspect	Powder for injection	Subcutaneous	100.0 Milligram			Asthma

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypoaesthesia	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Paraesthesia	v.24.1	
Product dose omission issue	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:09:42 AM
Initial Received Date:	2021-09-30 to 2021-12-30
Latest Received Date:	N/A
Total Number of Reports:	197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_05049634	0	2021-12-22	2021-12-22	MAH	202101766706	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
67 Years	Male	172 Centimeter	61 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BRODALUMAB	Suspect		Subcutaneous	210.0 Milligram	1 every 1 Weeks		Psoriasis
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
VENTOLIN [SALBUTAMOL]	Concomitant		Inhalation				
VITAMIN D	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anxiety	v.24.1	
Cheilitis	v.24.1	
Heart rate increased	v.24.1	
Hypertension	v.24.1	
Inappropriate schedule of product administration	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Off label use	v.24.1	
Patient dissatisfaction with treatment	v.24.1	
Psoriasis	v.24.1	
Skin infection	v.24.1	
Skin lesion	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2022-05-07 - 01:09:42 AM
Initial Received Date:	2021-09-30 to 2021-12-30
Latest Received Date:	N/A
Total Number of Reports:	197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_05053755	0	2021-12-23	2021-12-23	MAH	202101766627	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
30 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETAMINOPHEN	Concomitant	NOT SPECIFIED	Oral			24.0 Days	Premedication
ACYCLOVIR	Suspect		Oral	200.0 Milligram	2 every 1 Days	3.0 Days	Premedication
ACYCLOVIR	Suspect		Oral	200.0 Milligram	2 every 1 Days	3.0 Days	Premedication
ALEMTUZUMAB	Suspect		Unknown	12.0 Milligram	1 every 1 Days	2.0 Days	Relapsing-remitting multiple sclerosis
ALEMTUZUMAB	Suspect	SOLUTION INTRAVENOUS	Intravenous drip	12.0 Milligram	1 every 1 Days	1.0 Days	Relapsing-remitting multiple sclerosis
ATIVAN	Concomitant	NOT SPECIFIED	Oral				Sleep disorder
BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE]	Concomitant		Oral	25.0 Milligram			Premedication

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CIMETIDINE	Concomitant	NOT SPECIFIED	Oral	200.0 Milligram		24.0 Days	Premedication
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
CYANOCOBALAMIN	Concomitant	NOT SPECIFIED	Oral				Fatigue
GRAVOL	Concomitant	NOT SPECIFIED	Unknown	50.0 Milligram			Premedication
METHYLPREDNISOLONE SODIUM SUCCINATE	Suspect		Intravenous (not otherwise specified)	1.0 Gram		3.0 Days	Premedication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal distension	v.24.1	
Abdominal pain	v.24.1	
Abdominal pain lower	v.24.1	
Anion gap decreased	v.24.1	
Anxiety	v.24.1	
Asthenia	v.24.1	
Bacterial test positive	v.24.1	
Band sensation	v.24.1	
Basedow's disease	v.24.1	
Blood calcium decreased	v.24.1	
Blood creatinine decreased	v.24.1	
Blood urine present	v.24.1	
Bradycardia	v.24.1	
Chest pain	v.24.1	
Cough	v.24.1	
Culture urine positive	v.24.1	
Cystitis	v.24.1	
Decreased appetite	v.24.1	
Dehydration	v.24.1	
Dental caries	v.24.1	
Depression	v.24.1	
Drug exposure before pregnancy	v.24.1	
Dry mouth	v.24.1	
Dysuria	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Ear pain	v.24.1	
Emotional disorder	v.24.1	
Eosinophil count increased	v.24.1	
Fatigue	v.24.1	
Feeling abnormal	v.24.1	
Fibrin D dimer increased	v.24.1	
Flushing	v.24.1	
Frustration tolerance decreased	v.24.1	
Gingival pain	v.24.1	
Haematocrit increased	v.24.1	
Haemoglobin increased	v.24.1	
Headache	v.24.1	
Hepatic infection	v.24.1	
Hypersomnia	v.24.1	
Hypoaesthesia	v.24.1	
Hypotension	v.24.1	
Ill-defined disorder	v.24.1	
Increased appetite	v.24.1	
Increased tendency to bruise	v.24.1	
Influenza	v.24.1	
Infrequent bowel movements	v.24.1	
Insomnia	v.24.1	
Limb discomfort	v.24.1	
Lymphocyte count decreased	v.24.1	
Malaise	v.24.1	
Mean cell haemoglobin increased	v.24.1	
Mean cell volume increased	v.24.1	
Mobility decreased	v.24.1	
Multiple sclerosis relapse	v.24.1	
Muscle spasms	v.24.1	
Muscle tightness	v.24.1	
Muscular weakness	v.24.1	
Nasopharyngitis	v.24.1	
Nausea	v.24.1	
Neutrophil count increased	v.24.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Nitrite urine present	v.24.1	
Oral pain	v.24.1	
Oropharyngeal pain	v.24.1	
Pain in extremity	v.24.1	
Peripheral coldness	v.24.1	
Pollakiuria	v.24.1	
Poor peripheral circulation	v.24.1	
Poor quality sleep	v.24.1	
Post procedural contusion	v.24.1	
Protein urine present	v.24.1	
Pruritus	v.24.1	
Red blood cell count decreased	v.24.1	
Red cell distribution width decreased	v.24.1	
Respiratory tract congestion	v.24.1	
Rhinorrhoea	v.24.1	
Sinus disorder	v.24.1	
Skin discolouration	v.24.1	
Specific gravity urine decreased	v.24.1	
Stress	v.24.1	
Swelling face	v.24.1	
Thyroid hormones increased	v.24.1	
Tremor	v.24.1	
Urinary retention	v.24.1	
Urinary tract infection	v.24.1	
Urine abnormality	v.24.1	
Urine ketone body present	v.24.1	
Urine odour abnormal	v.24.1	
Urobilinogen urine increased	v.24.1	
Urticaria	v.24.1	
Vomiting	v.24.1	
Weight decreased	v.24.1	
White blood cells urine positive	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
Initial Received Date: 2021-09-30 to 2021-12-30
Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_05053904	0	2021-12-23	2021-12-23	MAH	202101767079	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
45 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
RISANKIZUMAB	Suspect		Subcutaneous	150.0 Milligram			Psoriasis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Psoriasis	v.24.1	
Therapeutic product effect incomplete	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2022-05-07 - 01:09:42 AM
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Latest Received Date: N/A
Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_05055708	0	2021-12-23	2021-12-23	MAH	202101767372	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Not Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
44 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Intramuscular		Total		COVID-19 immunisation
TYSABRI	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	300.0 Milligram	1 every 1 Months		Multiple sclerosis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Acarodermatitis	v.24.1	
Fatigue	v.24.1	
Irritability	v.24.1	
Perennial allergy	v.24.1	
Therapeutic response shortened	v.24.1	
Urticaria	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

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Total Number of Reports: 197 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_05058799	0	2021-12-24	2021-12-24	MAH	CANSL2021203939	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
32 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_05083405

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				Prophylaxis
ENBREL	Suspect		Unknown	50.0 Milligram	1 every 1 Weeks		Psoriatic arthropathy

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

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Latest Received Date: N/A
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Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_05065420	0	2021-12-27	2021-12-27	MAH	CA2021262882	Study	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
69 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	
Linked	
Linked	E2B_02053932

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BREO ELLIPTA	Concomitant	INHALATION	Unknown				Product used for unknown indication
COVID-19 VACCINE	Suspect		Unknown				COVID-19 prophylaxis
MEPOLIZUMAB	Suspect		Subcutaneous	100.0 Milligram			Asthma
PREDNISONE	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication
PULMICORT	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
SINGULAIR	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication
SPIRIVA	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication
VENTOLIN	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Atrial fibrillation	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Pneumonia	v.24.1	
Product dose omission issue	v.24.1	
Renal failure	v.24.1	
Staphylococcal infection	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

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Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_05071619	0	2021-12-28	2021-12-28	MAH	MYERS SQUIBB COMPANY	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
65 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_02375770
Linked	
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				Product used for unknown indication, COVID-19 immunisation
COVID-19 VACCINE	Suspect		Unknown				Product used for unknown indication, COVID-19 immunisation
ORENCIA	Suspect		Intravenous (not otherwise specified)	500.0 Milligram	1 every 1 Months		Rheumatoid arthritis

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
SYNTHROID	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication
VENTOLIN [SALBUTAMOL]	Concomitant		Unknown				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Eye infection viral	v.24.1	
Eye pruritus	v.24.1	
Eye swelling	v.24.1	
Glaucoma	v.24.1	
Headache	v.24.1	
Inappropriate schedule of product administration	v.24.1	
Malaise	v.24.1	
Tremor	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

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Latest Received Date: N/A
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Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_05082770	0	2021-12-30	2021-12-30	MAH	20211249874	Spontaneous	Other health professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
28 Years	Female			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect	Unknown	Unknown				Immunisation
COVID-19 VACCINE	Suspect	Unknown	Unknown				Immunisation
COVID-19 VACCINE	Suspect		Unknown				Immunisation
STELARA	Suspect	SOLUTION SUBCUTANEOUS	Subcutaneous				Crohn's disease

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthropathy	v.24.1	
Crohn's disease	v.24.1	
Drug ineffective	v.24.1	

Canada Vigilance
Summary of Reported Adverse Reactions

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Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_05083405	0	2021-12-30	2021-12-30	MAH	202101853719	Study	

Serious report?	Death:	No	Disability:	No	Congenital Anomaly:	No
Serious	Life Threatening:	No	Hospitalization:	Yes	Other Medically Important Conditions:	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
32 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Duplicate	E2B_05058799

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
COVID-19 VACCINE	Suspect		Unknown				COVID-19 immunisation
ENBREL	Suspect		Unknown	50.0 Milligram	1 every 1 Weeks		Psoriatic arthropathy

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.24.1	