Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-10-08 - 03:32:54 PM
Initial Received Date: 2022-05-01 to 2024-05-30
Latest Received Date: N/A
Total Number of Reports: 14 Report(s)

Report Information

***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
001012819	0	2022-08-09	2022-08-09	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
48 Years	Male	181 Centimeter	81 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					
BENADRYL	Concomitant	NOT SPECIFIED					
MOXIFLOXACIN	Concomitant	NOT SPECIFIED					
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	35.0 Gram	1 every 4 Weeks		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypersensitivity	v.27.0	
Transfusion reaction	v.27.0	

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001029898	0	2022-12-19	2022-12-19	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
86 Years	Female	153 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)
PANZYGA	Suspect	SOLUTION INTRAVENOUS		10.0 Gram	Once		Secondary immunodeficiency

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.27.0	
Chills	v.27.0	
Dyspnoea	v.27.0	

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Report Information

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001030980	2	2023-01-03	2023-10-02	MAH		Spontaneous	Other 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
67 Years	Female	152 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)
BACTRIM	Concomitant	NOT SPECIFIED					
CALCIUM CARBONATE	Concomitant	NOT SPECIFIED					
PANTOPRAZOLE	Concomitant	NOT SPECIFIED					
PANZYGA ALSO KNOW AS IMMUNE GLOBULIN (HUMAN)	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	30.0 Gram		5.0 Minutes	Myositis
PREDNISONE	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.27.0	
Breath sounds abnormal	v.27.0	
Dyspnoea	v.27.0	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Flushing	v.27.0	
Hypertension	v.27.0	
Hypotension	v.27.0	
Hypoxia	v.27.0	
Tachycardia	v.27.0	