Health Canada Santé Canada

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2024-12-16 - 06:01:42 AM
Initial Received Date:	1965-01-01 to 2024-08-31
Latest Received Date:	N/A
Total Number of Reports:	173 Report(s)

Brand Name/Active Ingredient: 'PANZYGA'
Search Date Criteria: 1965-01-01 to 2024-08-31
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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Report Information

***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000694440	1	2017-03-24	2017-04-04	Hospital		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
43 Years	Female	164 Centimeter	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)
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intracavernous	60.0 Gram	1 every 8 Months		Immune thrombocytopenia

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Throat irritation	v.27.1	
Urticaria	v.27.1	

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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
000695154	0	2017-04-06	2017-04-06	MAH	NGAM-003-17-CA	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
43 Years	Female	164 Centimeter	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)
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	60.0 Gram	Total		Immune thrombocytopenia

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Throat irritation	v.27.1	
Urticaria	v.27.1	

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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
000697271	1	2017-05-18	2017-05-30	MAH	NGAM-008-17-CA	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
43 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)
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	35.0 Gram	1 every 1 Days		Secondary immunodeficiency

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Condition aggravated	v.27.1	
Dyspnoea	v.27.1	
Tachycardia	v.27.1	
Tachypnoea	v.27.1	

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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
000697502	2	2017-05-24	2017-06-22	MAH	NGAM-009-17-CA	Spontaneous	Other 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
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)
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	50.0 Gram	1 every 1 Days	2.0 Days	Eosinophilic fasciitis
ZOPICLONE	Concomitant	Tablets					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Meningitis aseptic	v.27.1	
Nausea	v.27.1	
Pain	v.27.1	
Vomiting	v.27.1	

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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
000697506	1	2017-05-24	2017-05-31	MAH	NGAM-010-17-CA	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	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** 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					
AMLODIPINE	Concomitant	Tablets					
ATORVASTATIN CALCIUM	Concomitant	Tablets					
DIPHENHYDRAMINE	Concomitant	NOT SPECIFIED					
HYDROCHLOROTHIAZIDE	Concomitant	Tablets					
JANUVIA	Concomitant	Tablets					
LOSARTAN	Concomitant	Tablets					
METHYLPREDNISOLONE NOS	Concomitant	NOT SPECIFIED					
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	40.0 Gram	1 every 1 Days		Secondary immunodeficiency
RANITIDINE	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Back pain	v.27.1	
Chest discomfort	v.27.1	
Chest pain	v.27.1	
Dysarthria	v.27.1	
Dyspnoea	v.27.1	
Headache	v.27.1	
Lip swelling	v.27.1	
Musculoskeletal stiffness	v.27.1	
Nasal congestion	v.27.1	
Paraesthesia oral	v.27.1	
Rash	v.27.1	
Sensation of foreign body	v.27.1	
Swollen tongue	v.27.1	
Vision blurred	v.27.1	

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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
000698047	0	2017-06-05	2017-06-05	Hospital		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
65 Years	Female	158 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)
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	1000.0 mg/kg	1 every 1 Days		Immune thrombocytopenia
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	1000.0 mg/kg	1 every 1 Days		Immune thrombocytopenia
RED BLOOD CELLS	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anti A antibody positive	v.27.1	
Anxiety	v.27.1	
Blood bilirubin increased	v.27.1	
Blood lactate dehydrogenase increased	v.27.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.27.1	
Coombs direct test positive	v.27.1	
Heart rate increased	v.27.1	
Hyperhidrosis	v.27.1	
Nausea	v.27.1	
Pyrexia	v.27.1	
Vomiting	v.27.1	

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000698066	0	2017-06-06	2017-06-06	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
31 Years	Female	165 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)
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	30.0 Gram	1 every 4 Weeks		Nasopharyngitis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain	v.27.1	
Back pain	v.27.1	
Chills	v.27.1	
Headache	v.27.1	

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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
000698480	0	2017-06-16	2017-06-16	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
46 Years	Female	171 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)
ACTONEL	Concomitant	Tablets					
CALCIUM	Concomitant	NOT SPECIFIED					
LORAZEPAM	Concomitant	NOT SPECIFIED					
METHOTREXATE	Concomitant	NOT SPECIFIED					
MULTIVITAMINE(S)	Concomitant	NOT SPECIFIED					
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	70.0 Gram	2 every 1 Months		Dermatomyositis
PREDNISONE	Concomitant	NOT SPECIFIED					
SULFATRIM	Concomitant	NOT SPECIFIED					
VITAMIN D	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pruritus	v.27.1	
Urticaria	v.27.1	

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000698501	2	2017-06-14	2017-12-13	MAH	NGAM-016-17-CA	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
31 Years	Female	165 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)
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	14.4 Gram			Immunodeficiency common variable

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain	v.27.1	
Back pain	v.27.1	
Chills	v.27.1	
Headache	v.27.1	
Maternal exposure during pregnancy	v.27.1	
Pyrexia	v.27.1	

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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
000698524	0	2017-06-14	2017-06-14	MAH	NGAM-014-17-CA	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	Female	170 Centimeter	46 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	Intravenous (not otherwise specified)	20.0 Gram	Total		Hypogammaglobulinaemia

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Flank pain	v.27.1	
Oxygen saturation decreased	v.27.1	

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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
000698573	1	2017-06-16	2018-01-19	MAH	NGAM-015-17-CA	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
65 Years	Female		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)
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	1000.0 mg/kg	Total		Immune thrombocytopenia
RED BLOOD CELLS	Suspect	NOT SPECIFIED	Unknown	2.0 Units	Total		Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Antibody test positive	v.27.1	
Anxiety	v.27.1	
Blood bilirubin increased	v.27.1	
Blood lactate dehydrogenase increased	v.27.1	
Chills	v.27.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Coombs direct test	v.27.1	
Delayed haemolytic transfusion reaction	v.27.1	
Heart rate increased	v.27.1	
Hyperhidrosis	v.27.1	
Nausea	v.27.1	
Pyrexia	v.27.1	
Vomiting	v.27.1	

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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
000699797	0	2017-07-07	2017-07-07	MAH	NGAM-019-17-CA	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
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)
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	13.0 Gram			Kidney transplant rejection

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dyspnoea	v.27.1	
Foaming at mouth	v.27.1	
Loss of consciousness	v.27.1	
Nausea	v.27.1	
Vomiting	v.27.1	

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000699799	1	2017-07-07	2017-07-24	MAH	GAM-150-17-CA	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
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)
BUPROPION	Concomitant	TABLET (EXTENDED-RELEASE)					
OCTAGAM 10% FOR I.V. INFUSION	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	25.0 Gram	1 every 1 Months		Secondary immunodeficiency
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	25.0 Gram	1 every 1 Months		Secondary immunodeficiency

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hepatitis B core antibody positive	v.27.1	
Hepatitis B surface antibody positive	v.27.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Suspected transmission of an infectious agent via product	v.27.1	

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000699972	1	2017-07-12	2017-08-01	MAH	NGAM-020-17-CA	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
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)
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	95.0 Gram	Total		Multiple sclerosis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.27.1	
Headache	v.27.1	
Nausea	v.27.1	
Vomiting	v.27.1	

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000700984	0	2017-08-01	2017-08-01	MAH	NGAM-029-17-CA	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
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)
CELECOXIB	Concomitant	Capsules					
DOMPERIDONE	Concomitant	Tablets					
HYDROCHLOROTHIAZIDE	Concomitant	Tablets					
LORAZEPAM	Concomitant	NOT SPECIFIED					
PANTOPRAZOLE	Concomitant	NOT SPECIFIED					
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	30.0 Milligram	1 every 1 Days		Chronic inflammatory demyelinating polyradiculoneuropathy
PREGABALIN	Concomitant	Capsules					
TRIAMCINOLONE	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain upper	v.27.1	
Asthenia	v.27.1	
Chills	v.27.1	
Dizziness	v.27.1	
Head discomfort	v.27.1	
Headache	v.27.1	
Hypertension	v.27.1	
Malaise	v.27.1	
Nausea	v.27.1	
Palpitations	v.27.1	
Vomiting	v.27.1	

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000701655	2	2017-08-18	2017-09-08	MAH	NGAM-036-17-CA	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
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)
ACETAMINOPHEN	Concomitant	NOT SPECIFIED					
AMLODIPINE	Concomitant	Tablets					
IPRATROPIUM	Concomitant	NOT SPECIFIED					
MAGNESIUM	Concomitant	NOT SPECIFIED					
METOPROLOL	Concomitant	NOT SPECIFIED					
METRONIDAZOLE	Concomitant	NOT SPECIFIED					
METRONIDAZOLE	Concomitant	NOT SPECIFIED					
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	10.0 Gram		75.0 Minutes	Clostridium difficile infection
POTASSIUM CHLORIDE	Concomitant	NOT SPECIFIED					
VANCOMYCIN	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypersensitivity	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000702366	0	2017-09-06	2017-09-06	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
46 Years	Female	171 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)
ACTONEL	Concomitant	Tablets					
APO SULFATRIM TAB	Concomitant	Tablets					
CALCIUM	Concomitant	NOT SPECIFIED					
DIPHENHYDRAMINE HYDROCHLORIDE INJECTION USP	Concomitant	LIQUID INTRAMUSCULAR					
LORAZEPAM	Concomitant	NOT SPECIFIED					
MULTIVITAMINE(S)	Concomitant	NOT SPECIFIED					
OCTAGAM 10% FOR I.V. INFUSION	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	10.0 Gram			Dermatomyositis
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	60.0 Gram			Dermatomyositis

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PREDNISONE	Concomitant	NOT SPECIFIED					
VITAMIN D	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood pressure increased	v.27.1	
Heart rate increased	v.27.1	
Rash erythematous	v.27.1	
Rash pruritic	v.27.1	
Urticaria	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000702762	0	2017-09-14	2017-09-14	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
57 Years	Male	67 Inch	214 Pound	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Duplicate	000713845

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BENADRYL	Concomitant	NOT SPECIFIED					
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	100.0 Gram	Cyclical		Myasthenia gravis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Urticaria	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000702969	0	2017-09-19	2017-09-19	MAH	NGAM-043-17-A	Spontaneous	Other 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
46 Years	Female	171 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)
CALCIUM	Concomitant	NOT SPECIFIED					
DIPHENHYDRAMINE	Concomitant	NOT SPECIFIED					
LORAZEPAM	Concomitant	NOT SPECIFIED					
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	70.0 Gram	1 every 1 Months		Dermatomyositis
PREDNISONE	Concomitant	NOT SPECIFIED					
RISEDRONATE (MANUFACTURER UNKNOWN)	Concomitant	NOT SPECIFIED					
SULFAMETHOXAZOLE AND TRIMETHOPRIM	Concomitant	NOT SPECIFIED					
VITAMIN D	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood pressure increased	v.27.1	
Heart rate increased	v.27.1	
Pruritus	v.27.1	
Rash	v.27.1	
Urticaria	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000703006	0	2017-09-19	2017-09-19	MAH	NGAM-039-17-CA	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
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)
DIPHENHYDRAMINE	Concomitant	NOT SPECIFIED					
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	30.0 Gram		55.0 Minutes	Secondary immunodeficiency
PIPERACILLIN AND TAZOBACTAM FOR INJECTION	Concomitant	POWDER FOR SOLUTION INTRAVENOUS					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.27.1	
Confusional state	v.27.1	
Pyrexia	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000703346	0	2017-09-27	2017-09-27	Hospital		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
55 Years	Female	157 Centimeter	79 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Duplicate	000713844

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	60.0 Gram	1 every 1 Days	2.0 Days	Immune thrombocytopenia

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Urticaria	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000703391	0	2017-09-28	2017-09-28	Hospital		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
52 Years	Female	164 Centimeter	87 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	Intravenous (not otherwise specified)	25.0 Gram	1 every 4 Weeks		Secondary immunodeficiency

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Back pain	v.27.1	
Blood pressure increased	v.27.1	
Chest pain	v.27.1	
Chills	v.27.1	
Dizziness	v.27.1	
Nausea	v.27.1	
Palpitations	v.27.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Vomiting	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000703406	0	2017-09-27	2017-09-27	MAH	NGAM-046-17-CA	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
70 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)
HUMALOG	Concomitant	Injection					
INSULIN	Concomitant	NOT SPECIFIED					
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	50.0 Gram	1 every 1 Weeks		Myasthenia gravis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood pressure increased	v.27.1	
Chest discomfort	v.27.1	
Headache	v.27.1	
Heart rate increased	v.27.1	
Malaise	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000703596	0	2017-10-03	2017-10-03	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
	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** 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	Intravenous (not otherwise specified)	20.0 ml	Once		Primary immunodeficiency syndrome

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000703841	0	2017-10-10	2017-10-10	Hospital		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
	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** 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	Intravenous (not otherwise specified)	200.0 ml			Abscess drainage
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	127.0 ml			Abscess drainage

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.27.1	
Febrile nonhaemolytic transfusion reaction	v.27.1	
Heart rate increased	v.27.1	
Hypoxia	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000703969	0	2017-10-11	2017-10-11	MAH	NGAM-047-17-CA	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
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)
ACETAMINOPHEN	Concomitant	NOT SPECIFIED					
DIPHENHYDRAMINE	Concomitant	NOT SPECIFIED					
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)			148.0 Minutes	Neutropenia
PRIVIGEN	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	30.0 Gram	Once		Neutropenia

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Febrile nonhaemolytic transfusion reaction	v.27.1	
Headache	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000704117	0	2017-10-13	2017-10-13	MAH	NGAM-049-17-CA	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			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** 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	Intravenous (not otherwise specified)	2.0 Gram	Total	30.0 Minutes	Primary immunodeficiency syndrome

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000704133	0	2017-10-13	2017-10-13	MAH	NGAM-051-17-CA	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
61 Years	Male	163 Centimeter	82 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)
DEXTROSE	Concomitant	NOT SPECIFIED					
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	30.0 Gram	1 every 1 Months	90.0 Minutes	Secondary immunodeficiency

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Febrile nonhaemolytic transfusion reaction	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000704164	0	2017-10-16	2017-10-16	Hospital		Spontaneous	Other health professional

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
55 Years	Female		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)
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	40.0 Gram	1 every 1 Months		Immunodeficiency

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.27.1	
Chest pain	v.27.1	
Headache	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000704354	0	2017-10-19	2017-10-19	MAH	NGAM-053-17-CA	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
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)
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	32.7 Gram	Once		Incisional drainage

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Febrile nonhaemolytic transfusion reaction	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000704805	1	2017-10-27	2018-02-02	MAH	NGAM-055-17-CA	Spontaneous	Other health professional

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

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)
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	7.0 Gram			Immunodeficiency

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.27.1	
Chest discomfort	v.27.1	
Depressed level of consciousness	v.27.1	
Swollen tongue	v.27.1	
Throat tightness	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000704894	0	2017-11-02	2017-11-02	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
56 Years	Female	150 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)
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	15.0 Gram	1 every 28 Days		Immunoglobulin therapy

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bronchospasm	v.27.1	
Chest discomfort	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000704895	0	2017-11-02	2017-11-02	Community		Spontaneous	Other 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
56 Years	Female	150 Centimeter	48 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Duplicate	000713840

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	15.0 Gram			Immunoglobulin therapy

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.27.1	
Migraine	v.27.1	
Visual impairment	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000704901	0	2017-10-31	2017-10-31	Hospital		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
30 Years	Female	147 Centimeter	46 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Duplicate	000705574

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	30.0 Gram	1 every 4 Weeks		Immune system disorder

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anxiety	v.27.1	
Back pain	v.27.1	
Chest pain	v.27.1	
Infusion related reaction	v.27.1	
Nausea	v.27.1	
Throat tightness	v.27.1	
Vomiting	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000704947	0	2017-11-01	2017-11-01	MAH	NGAM-050-17-CA	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
30 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					
FOLIC ACID	Concomitant	NOT SPECIFIED					
PANTOPRAZOLE	Concomitant	NOT SPECIFIED					
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	90.0 Gram	Total	178.0 Minutes	Immune thrombocytopenia
PREDNISONE	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pruritus	v.27.1	
Rash	v.27.1	
Urticaria	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000704990	1	2017-11-02	2018-01-05	MAH	NGAM-035-17-CA	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
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)
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	17.7 Gram	Total	110.0 Minutes	Encephalomyelitis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactoid reaction	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000705242	0	2017-11-08	2017-11-08	MAH	NGAM-058-17-CA	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
78 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)
AZITHROMYCIN	Concomitant	NOT SPECIFIED					
LOVENOX	Concomitant	SOLUTION SUBCUTANEOUS					
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	16.0 Gram		80.0 Minutes	Secondary immunodeficiency
TAZOCIN	Concomitant	POWDER FOR SOLUTION INTRAVENOUS					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood pressure increased	v.27.1	
Chills	v.27.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Heart rate increased	v.27.1	
Respiratory distress	v.27.1	
Skin disorder	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000705251	0	2017-11-08	2017-11-08	MAH	NGAM-060-17-CA	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	164 Centimeter	87 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	Intravenous (not otherwise specified)	25.0 Gram	1 every 4 Weeks		Secondary immunodeficiency

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Back pain	v.27.1	
Blood pressure increased	v.27.1	
Chest pain	v.27.1	
Chills	v.27.1	
Dizziness	v.27.1	
Heart rate increased	v.27.1	
Nausea	v.27.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Vomiting	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000705490	0	2017-11-15	2017-11-15	MAH	NGAM-068-17-CA	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
56 Years	Female	150 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)
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	15.0 Gram	1 every 28 Days		Primary immunodeficiency syndrome

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bronchospasm	v.27.1	
Chest discomfort	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000705574	0	2017-11-15	2017-11-15	MAH	NGAM-059-17-CA	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
30 Years	Female	147 Centimeter	46 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Duplicate	000704901

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	30.0 Gram	1 every 4 Weeks		Immunodeficiency common variable

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anxiety	v.27.1	
Back pain	v.27.1	
Chest pain	v.27.1	
Nausea	v.27.1	
Throat tightness	v.27.1	
Vomiting	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000706202	0	2017-11-29	2017-11-29	MAH	NGAM-074-17-CA	Spontaneous	Other 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
19 Years	Male		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)
IBUPROFEN	Concomitant	NOT SPECIFIED					
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	60.0 Gram	Total	170.0 Minutes	Thrombocytopenia
VYVANSE	Concomitant	Capsules					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood pressure diastolic decreased	v.27.1	
CSF protein increased	v.27.1	
Headache	v.27.1	
Meningitis aseptic	v.27.1	
Nausea	v.27.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Vomiting	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000706386	1	2017-12-05	2017-12-20	MAH	NGAM-075-17-CA	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
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)
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	8.7 Gram		95.0 Minutes	Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Alpha haemolytic streptococcal infection	v.27.1	
Pyrexia	v.27.1	
Suspected transmission of an infectious agent via product	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000706546	1	2017-12-08	2018-05-28	Hospital		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
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)
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	90.0 Gram	1 every 3 Weeks	75.0 Minutes	Immunodeficiency common variable

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood culture negative	v.27.1	
Chills	v.27.1	
Hypertension	v.27.1	
Infusion related reaction	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000706563	0	2017-12-11	2017-12-11	Hospital		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
6 Years	Male	120 Centimeter	20 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					
ACETYLSALICYLIC ACID	Concomitant	NOT SPECIFIED					
AMOXICILLIN	Concomitant	NOT SPECIFIED					
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	40.0 Gram			Kawasaki's disease

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bradycardia	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000707175	0	2017-12-22	2017-12-22	MAH	NGAM-077-17-CA	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
6 Years	Male	120 Centimeter	20 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					
ACETYLSALICYLIC ACID	Concomitant	NOT SPECIFIED					
AMOXICILLIN	Concomitant	NOT SPECIFIED					
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	30.0 Gram			Kawasaki's disease

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood lactate dehydrogenase increased	v.27.1	
Bradycardia	v.27.1	
Heart rate irregular	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000709078	4	2018-02-05	2018-09-27	MAH	NGAM-002-18-CA	Spontaneous	Other 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
9 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** 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	Intravenous (not otherwise specified)	57.0 Gram	Total		Kawasaki's disease

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain	v.27.1	
Anti A antibody positive	v.27.1	
Blood urine present	v.27.1	
Haemoglobin decreased	v.27.1	
Haemolysis	v.27.1	
Headache	v.27.1	
Oedema	v.27.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pyrexia	v.27.1	
Reticulocyte count increased	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000709440	0	2018-02-13	2018-02-13	MAH	NGAM-011-18-CA	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
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)
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	70.0 Gram	Total	4.0 Hours	Chronic inflammatory demyelinating polyradiculoneuropathy

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic transfusion reaction	v.27.1	
Blood pressure increased	v.27.1	
Respiratory rate increased	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000709443	0	2018-02-14	2018-02-14	MAH	NGAM-015-18-CA	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
6 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** 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	Intravenous (not otherwise specified)	20.0 Gram	Total	6.0 Hours	Immune thrombocytopenia

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Meningitis aseptic	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000709474	0	2018-02-16	2018-02-16	MAH	NGAM-019-18-CA	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
77 Years	Male	178 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)
ALBUTEROL	Concomitant	NOT SPECIFIED					
CALCIUM	Concomitant	NOT SPECIFIED					
LORAZEPAM	Concomitant	NOT SPECIFIED					
METOCLOPRAMIDE	Concomitant	NOT SPECIFIED					
PANTOPRAZOLE	Concomitant	NOT SPECIFIED					
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	175.0 Gram	Total	135.0 Minutes	Immune thrombocytopenia
POLYETHYLENE GLYCOL	Concomitant	NOT SPECIFIED					
PREDNISONE	Concomitant	NOT SPECIFIED					
RISEDRONATE (MANUFACTURER UNKNOWN)	Concomitant	NOT SPECIFIED					
SALBUTAMOL	Concomitant	NOT SPECIFIED					

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
SEEBRI BREEZHALER	Concomitant	Capsules					
TACROLIMUS	Concomitant	Capsules					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain	v.27.1	
Aortic arteriosclerosis	v.27.1	
Blood pressure increased	v.27.1	
Dyspnoea	v.27.1	
Erythema	v.27.1	
Lung hyperinflation	v.27.1	
Pain	v.27.1	
Rash	v.27.1	
Tachycardia	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000709512	0	2018-02-20	2018-02-20	MAH	NGAM-020-18-CA	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
15 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)
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	45.0 Gram	1 every 1 Months	4.0 Hours	Immunodeficiency

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.27.1	
Neck pain	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000710295	0	2018-03-07	2018-03-07	MAH	NGAM-027-18-CA	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
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)
LORAZEPAM	Concomitant	NOT SPECIFIED					
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	25.0 Gram	1 every 3 Weeks		Plasma cell myeloma

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Atrial flutter	v.27.1	
Chills	v.27.1	
Dyspnoea	v.27.1	
Hyperhidrosis	v.27.1	
Hypertension	v.27.1	
Oxygen saturation decreased	v.27.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Tachycardia	v.27.1	
Tachypnoea	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000711152	0	2018-03-28	2018-03-28	MAH	NGAM-039-18-CA	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
78 Years	Female		44 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	Intravenous (not otherwise specified)	20.0 Gram	1 every 4 Weeks		Hypogammaglobulinaemia

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.27.1	
Discomfort	v.27.1	
Feeling abnormal	v.27.1	
Headache	v.27.1	
Heart rate increased	v.27.1	
Hypertension	v.27.1	
Oxygen saturation decreased	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000711158	0	2018-03-28	2018-03-28	MAH	NGAM-037-18-CA	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
78 Years	Male	179 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)
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)				Immune thrombocytopenia

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anti A antibody positive	v.27.1	
Blood lactate dehydrogenase increased	v.27.1	
Coombs direct test positive	v.27.1	
Delayed haemolytic transfusion reaction	v.27.1	
Haemoglobin decreased	v.27.1	
Reticulocyte count increased	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000711296	0	2018-04-03	2018-04-03	MAH	NGAM-042-18-CA	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
82 Years	Male		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)
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	30.0 Gram	Total	75.0 Minutes	Rheumatoid arthritis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood pressure increased	v.27.1	
Chest discomfort	v.27.1	
Chest pain	v.27.1	
Chills	v.27.1	
Febrile nonhaemolytic transfusion reaction	v.27.1	
Injection site erythema	v.27.1	
Pyrexia	v.27.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Tremor	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000711504	0	2018-04-06	2018-04-06	Hospital		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
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)
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	80.0 ml	Once		
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Febrile nonhaemolytic transfusion reaction	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000711630	0	2018-04-10	2018-04-10	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
66 Years	Male	190 Centimeter	126 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	Capsules					
GRAVOL	Concomitant	Tablets					
NAPROXEN	Concomitant	Tablets					
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	300.0 ml	Once		
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	300.0 ml	Once		
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	300.0 ml	Once		

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	100.0 ml	Once		
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	300.0 ml	Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypersensitivity	v.27.1	
Injection site rash	v.27.1	
Urticaria	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000712310	0	2018-04-17	2018-04-17	MAH	NGAM-049-18-CA	Spontaneous	Other 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
83 Years	Male		91 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)
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	35.0 Gram	Total	90.0 Minutes	Immune thrombocytopenia

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood pressure increased	v.27.1	
Chills	v.27.1	
Dyspnoea	v.27.1	
Hypothermia	v.27.1	
Oxygen saturation decreased	v.27.1	
Tremor	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000712582	1	2018-04-30	2018-06-04	MAH	NGAM-014-18-CA	Spontaneous	Other 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
13 Months	Male		8 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	Intravenous (not otherwise specified)	17.5 Gram	Total		Kawasaki's disease

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Haemoglobin decreased	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000712901	1	2018-05-07	2018-05-23	MAH	NGAM-054-18-CA	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
79 Years	Male	173 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)
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	30.0 Gram	1 every 5 Weeks	94.0 Minutes	Primary immunodeficiency syndrome

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood pressure increased	v.27.1	
Chills	v.27.1	
Dyspnoea	v.27.1	
Febrile nonhaemolytic transfusion reaction	v.27.1	
Oxygen saturation decreased	v.27.1	
Productive cough	v.27.1	
Respiratory rate increased	v.27.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Tachycardia	v.27.1	
Tremor	v.27.1	
Wheezing	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000713126	1	2018-05-08	2018-09-27	MAH	NGAM-053-18-CA	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
64 Years	Female	165 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)
ALENDRONATE	Concomitant	Tablets					
APO-FERROUS SULFATE	Concomitant	TABLET (ENTERIC-COATED)					
CALCIUM	Concomitant	NOT SPECIFIED					
COUMADIN	Concomitant	Tablets					
DIPHENHYDRAMINE	Concomitant	NOT SPECIFIED					
DOCUSATE SODIUM	Concomitant	NOT SPECIFIED					
HYDROXYCHLOROQUINE	Concomitant	NOT SPECIFIED					
METHYLPREDNISOLONE NOS	Concomitant	NOT SPECIFIED					
OXAZEPAM	Concomitant	Tablets					
PANTOPRAZOLE	Concomitant	NOT SPECIFIED					

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	20.0 Gram	Total	230.0 Minutes	Hodgkin's disease
PREDNISONE	Concomitant	NOT SPECIFIED					
SENNOSIDES	Concomitant	NOT SPECIFIED					
VITAMIN D	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain	v.27.1	
Back pain	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
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Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000713150	0	2018-05-09	2018-05-09	MAH	NGAM-058-18-CA	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
52 Years	Male	173 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)
ACETAMINOPHEN	Concomitant	NOT SPECIFIED					
DIPHENHYDRAMINE	Concomitant	NOT SPECIFIED					
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)				Chronic inflammatory demyelinating polyradiculoneuropathy

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.27.1	
Heart rate increased	v.27.1	
Hypotension	v.27.1	
Loss of consciousness	v.27.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Oxygen saturation decreased	v.27.1	
Pyrexia	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000713303	0	2018-05-14	2018-05-14	MAH	NGAM-064-18-CA	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	Male		89 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)
METHYLPREDNISOLONE NOS	Concomitant	NOT SPECIFIED					
PANTOPRAZOLE	Concomitant	NOT SPECIFIED					
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	180.0 Gram	Total		Immune thrombocytopenia
SULFAMETHOXAZOLE AND TRIMETHOPRIM	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaemia	v.27.1	
Coombs test positive	v.27.1	
Haemoglobin decreased	v.27.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Haemolysis	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
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Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000713357	2	2018-05-15	2018-08-03	MAH	NGAM-066-18-CA	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
74 Years	Female	157 Centimeter	82 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	Intravenous (not otherwise specified)	80.0 Gram	1 every 4 Weeks		Immune thrombocytopenia

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood pressure increased	v.27.1	
Haemoglobinuria	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000713544	1	2018-05-22	2018-05-30	MAH	NGAM-070-18-CA	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
40 Years	Female		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)
DIPHENHYDRAMINE	Concomitant	NOT SPECIFIED					
HYDROCORTISONE	Concomitant	NOT SPECIFIED					
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	40.0 Gram	Total		Clostridium difficile colitis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Body temperature increased	v.27.1	
Chills	v.27.1	
Condition aggravated	v.27.1	
Face oedema	v.27.1	
Oropharyngeal pain	v.27.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Tachycardia	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000716091	0	2018-07-25	2018-07-25	MAH	NGAM-093-18-CA	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
17 Years	Female	167 Centimeter	80 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)
ADCETRIS	Concomitant	POWDER FOR SOLUTION INTRAVENOUS					
FENTANYL	Concomitant	NOT SPECIFIED					
LORAZEPAM	Concomitant	NOT SPECIFIED					
MIDAZOLAM (UNKNOWN)	Concomitant						
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	55.0 Gram	1 every 1 Days	160.0 Minutes	Guillain-Barre syndrome

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood pressure diastolic decreased	v.27.1	
Chills	v.27.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.27.1	
Heart rate increased	v.27.1	
Meningitis aseptic	v.27.1	
Nausea	v.27.1	
Pyrexia	v.27.1	
Vomiting	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000717005	0	2018-08-22	2018-08-22	MAH	NGAM-105-18-CA	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
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)
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	50.0 Gram	Total	85.0 Minutes	Urticaria

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Back pain	v.27.1	
Chills	v.27.1	
Condition aggravated	v.27.1	
Febrile nonhaemolytic transfusion reaction	v.27.1	
Headache	v.27.1	
Heart rate increased	v.27.1	
Hypertension	v.27.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Oropharyngeal pain	v.27.1	
Urticaria	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000717114	0	2018-08-24	2018-08-24	MAH	NGAM-112-18-CA	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
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)
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	50.0 Gram	1 every 1 Months		Secondary immunodeficiency

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.27.1	
Condition aggravated	v.27.1	
Febrile nonhaemolytic transfusion reaction	v.27.1	
Headache	v.27.1	
Hypertension	v.27.1	
Hyperthermia	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000717119	1	2018-08-24	2018-10-04	MAH	NGAM-108-18-CA	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
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)
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	80.0 Gram	Total	1.0 Hours	Hypogammaglobulinaemia

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Back pain	v.27.1	
Chills	v.27.1	
Haemolysis	v.27.1	
Oxygen saturation decreased	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000717121	0	2018-08-24	2018-08-24	MAH	NGAM-114-18-CA	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
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)
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	25.0 Gram	Total		Secondary immunodeficiency

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain upper	v.27.1	
Back pain	v.27.1	
Hypertension	v.27.1	
Tremor	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000717127	0	2018-08-24	2018-08-24	MAH	NGAM-109-18-CA	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
20 Months	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					
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	125.0 ml	Total	96.0 Minutes	Immune thrombocytopenia

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.27.1	
Febrile nonhaemolytic transfusion reaction	v.27.1	
Oxygen saturation decreased	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000717454	0	2018-09-04	2018-09-04	MAH	NGAM-115-18-CA	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
83 Years	Female	152 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)
DIPHENHYDRAMINE	Concomitant	NOT SPECIFIED					
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	15.0 Gram	1 every 1 Months		Hypogammaglobulinaemia

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Back pain	v.27.1	
Body temperature increased	v.27.1	
Chills	v.27.1	
Hypertension	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000718185	2	2018-09-25	2018-10-25	MAH	NGAM-121-18-CA	Spontaneous	Other 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
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)
ACETAMINOPHEN	Concomitant	NOT SPECIFIED					
ACETYLSALICYLIC ACID	Concomitant	NOT SPECIFIED					
CITALOPRAM	Concomitant	Tablets					
CLOPIDOGREL	Concomitant	Tablets					
DEXLANSOPRAZOLE	Concomitant						
DIMENHYDRINATE	Concomitant	NOT SPECIFIED					
IBUPROFEN	Concomitant	NOT SPECIFIED					
INSULIN	Concomitant	NOT SPECIFIED					
JARDIANCE	Concomitant						
LEVOTHYROXINE	Concomitant	NOT SPECIFIED					
LINAGLIPTIN	Concomitant						
METFORMIN	Concomitant	Tablets					

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
METOCLOPRAMIDE	Concomitant	NOT SPECIFIED					
METOPROLOL	Concomitant	NOT SPECIFIED					
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	40.0 Gram	1 every 1 Days		Encephalitis autoimmune
PERINDOPRIL	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arteriovenous fistula	v.27.1	
Cerebrovascular accident	v.27.1	
Hemiparesis	v.27.1	
Pain	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000718804	1	2018-10-11	2018-11-05	MAH	NGAM-130-18-CA	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
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)
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	65.0 Gram	Total	290.0 Minutes	Immune thrombocytopenia

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anti A antibody positive	v.27.1	
Haemoglobin decreased	v.27.1	
Hepatitis B core antibody positive	v.27.1	
Seroconversion test positive	v.27.1	
Transfusion reaction	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000719429	0	2018-10-29	2018-10-29	MAH	NGAM-147-18-CA	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
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					
DOCUSATE SODIUM	Concomitant	NOT SPECIFIED					
ENOXAPARIN	Concomitant	Injection					
HYDROCORTISONE	Concomitant	NOT SPECIFIED					
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	54.0 Gram	Total	105.0 Minutes	Mononeuropathy multiplex
POLYETHYLENE GLYCOL	Concomitant	NOT SPECIFIED					
SENNOSIDES	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Body temperature increased	v.27.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.27.1	
Hypertension	v.27.1	
Tachycardia	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000720047	1	2018-11-21	2019-08-14	MAH	NGAM-168-18-CA	Spontaneous	Physician

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
67 Years	Female	154 Centimeter	76 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)
CEFPROZIL	Concomitant	NOT SPECIFIED					
CEFTRIAXONE FOR INJECTION USP	Concomitant	POWDER FOR SOLUTION INTRAMUSCULAR					
DOXYCYCLINE	Concomitant	NOT SPECIFIED					
MEROPENEM	Concomitant	POWDER FOR SOLUTION INTRAVENOUS					
PANTOPRAZOLE	Concomitant	NOT SPECIFIED					
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)				Neuropathy peripheral
PREGABALIN	Concomitant	Capsules					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood pressure increased	v.27.1	
Body temperature increased	v.27.1	
Chills	v.27.1	
Dyspnoea	v.27.1	
Nausea	v.27.1	
Pyrexia	v.27.1	
Respiratory rate increased	v.27.1	
Tachycardia	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000720672	0	2018-12-11	2018-12-11	MAH	NGAM-153-18-CA	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
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)
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	65.0 Gram	Total		Thrombocytopenic purpura
PLATELETS	Suspect	NOT SPECIFIED	Unknown	250.0 ml	Total		Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaemia	v.27.1	
Chills	v.27.1	
Confusional state	v.27.1	
Faeces discoloured	v.27.1	
Haemoglobinuria	v.27.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Haemoptysis	v.27.1	
Pyrexia	v.27.1	
Tachycardia	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000721026	0	2018-12-20	2018-12-20	MAH	NGAM-183-18-CA	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
73 Years	Female	158 Centimeter	93 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	Intravenous (not otherwise specified)	5.0 Gram	Total		Hypogammaglobulinaemia

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood pressure decreased	v.27.1	
Chest pain	v.27.1	
Erythema	v.27.1	
Hypertension	v.27.1	
Hypoxia	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000721432	0	2019-01-08	2019-01-08	MAH	NGAM-188-18-CA	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
83 Years	Female		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)
BISOPROLOL	Concomitant	Tablets					
CALCIUM	Concomitant	NOT SPECIFIED					
PANTOPRAZOLE	Concomitant	NOT SPECIFIED					
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	20.0 Gram	1 every 4 Weeks	80.0 Minutes	Hypogammaglobulinaemia
VITAMIN D	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Back pain	v.27.1	
Chills	v.27.1	
Cyanosis	v.27.1	
Hypersensitivity	v.27.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypertension	v.27.1	
Hypoxia	v.27.1	
Tachycardia	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000722430	0	2019-02-05	2019-02-05	MAH	NGAM-012-19-CA	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
65 Years	Female	172 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)
ACETAMINOPHEN	Concomitant	NOT SPECIFIED					
DEXAMETHASONE	Concomitant	NOT SPECIFIED					
DICYCLOMINE HYDROCHLORIDE USP	Concomitant	NOT SPECIFIED					
DIPHENHYDRAMINE	Concomitant	NOT SPECIFIED					
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	140.0 Gram	Total		Muscular weakness
PYRIDOSTIGMINE BROMIDE	Concomitant	NOT SPECIFIED					
RIVAROXABAN (BAY59-7939) VS. ASA	Concomitant						
SYMBICORT	Concomitant	Powder					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain upper	v.27.1	
Asthenia	v.27.1	
Chest pain	v.27.1	
Chills	v.27.1	
Drug intolerance	v.27.1	
Electrocardiogram T wave abnormal	v.27.1	
Fatigue	v.27.1	
Headache	v.27.1	
Hypertension	v.27.1	
Pallor	v.27.1	
Syncope	v.27.1	
Tremor	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000722754	1	2019-02-14	2019-04-10	MAH	NGAM-016-19-CA	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
49 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)
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	74.0 Gram	Total		Toxic shock syndrome

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anxiety	v.27.1	
Chest pain	v.27.1	
Chills	v.27.1	
Cough	v.27.1	
Dysphagia	v.27.1	
Dyspnoea	v.27.1	
Hypersensitivity	v.27.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypotension	v.27.1	
Oxygen saturation decreased	v.27.1	
Pulmonary oedema	v.27.1	
Tachycardia	v.27.1	
Tachypnoea	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000722903	0	2019-02-20	2019-02-20	MAH	NGAM-023-19-CA	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
61 Years	Female		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)
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	50.0 Gram			Immune thrombocytopenia

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood pressure increased	v.27.1	
Feeling cold	v.27.1	
Headache	v.27.1	
Meningitis aseptic	v.27.1	
Neck pain	v.27.1	
Pyrexia	v.27.1	
Tremor	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000722907	0	2019-02-21	2019-02-21	MAH	NGAM-017-19-CA	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
15 Years	Female	161 Centimeter	87 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	Intravenous (not otherwise specified)	30.0 Milligram	Total		Immune thrombocytopenia

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.27.1	
Dyspnoea	v.27.1	
Febrile nonhaemolytic transfusion reaction	v.27.1	
Headache	v.27.1	
Hypertension	v.27.1	
Loss of consciousness	v.27.1	
Nausea	v.27.1	
Oxygen saturation decreased	v.27.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Vomiting	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000723306	0	2019-03-01	2019-03-01	MAH	NGAM-030-19-CA	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
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)
ALTEPLASE	Concomitant	LIQUID INTRAVENOUS					
CEFTRIAXONE SODIUM FOR INJECTION BP	Concomitant						
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	50.0 Gram	Total		Immunodeficiency
PIPERACILLIN/TAZOBACTAM	Concomitant	NOT SPECIFIED					
PREDNISONE	Concomitant	NOT SPECIFIED					
VANCOMYCIN	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.27.1	
Blood pressure increased	v.27.1	
Chills	v.27.1	
Dyspnoea	v.27.1	
Hyperhidrosis	v.27.1	
Oxygen saturation decreased	v.27.1	
Pyrexia	v.27.1	
Swelling of eyelid	v.27.1	
Tachycardia	v.27.1	
Tremor	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000723342	0	2019-03-06	2019-03-06	MAH	NGAM-036-19-CA	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
56 Years	Female	147 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)
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	30.0 Gram	1 every 4 Weeks		Hypogammaglobulinaemia

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.27.1	
Erythema	v.27.1	
Febrile nonhaemolytic transfusion reaction	v.27.1	
Hypertension	v.27.1	
Hyperthermia	v.27.1	
Hypopnoea	v.27.1	
Tachycardia	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000723524	2	2019-03-11	2019-04-29	MAH	NGAM-035-19-CA	Spontaneous	Other 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
29 Years	Female	170 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)
DEXAMETHASONE	Concomitant	NOT SPECIFIED					
ECHINACEA	Concomitant	NOT SPECIFIED					
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	85.0 Gram	Total		Immune thrombocytopenia
VITAMIN C	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaemia	v.27.1	
Anti A antibody positive	v.27.1	
Body temperature increased	v.27.1	
Delayed haemolytic transfusion reaction	v.27.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Drug intolerance	v.27.1	
Jaundice	v.27.1	
Malaise	v.27.1	
Pain in extremity	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000723799	2	2019-03-19	2019-08-18	MAH	NGAM-040-19-CA	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
84 Years	Female	148 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)
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	20.0 Gram	1 every 6 Weeks		Secondary immunodeficiency

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.27.1	
Hypertension	v.27.1	
Hypoxia	v.27.1	
Tremor	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000725335	0	2019-04-25	2019-04-25	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
60 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Duplicate	000909260

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	80.0 ml	Once		Pelvic inflammatory disease

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.27.1	
Blood potassium decreased	v.27.1	
Blood pressure increased	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000725404	1	2019-04-26	2019-05-21	MAH	NGAM-053-19-CA	Spontaneous	Other 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
50 Years	Male		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)
BUPROPION	Concomitant	TABLET (EXTENDED-RELEASE)					
CEFTRIAXONE FOR INJECTION USP	Concomitant	POWDER FOR SOLUTION INTRAMUSCULAR					
CLINDAMYCIN	Concomitant	NOT SPECIFIED					
FLUOXETINE	Concomitant	NOT SPECIFIED					
OXYCODONE	Concomitant	NOT SPECIFIED					
PANTOPRAZOLE	Concomitant	NOT SPECIFIED					
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	20.0 Gram	Total		General physical health deterioration
PREGABALIN	Concomitant	Capsules					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.27.1	
Chromaturia	v.27.1	
Dyspnoea	v.27.1	
Haptoglobin increased	v.27.1	
Hypertension	v.27.1	
Hypoxia	v.27.1	
Nausea	v.27.1	
Pleuritic pain	v.27.1	
Tachycardia	v.27.1	
Tachypnoea	v.27.1	
Transfusion-related acute lung injury	v.27.1	
Vomiting	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000725886	1	2019-05-10	2019-05-29	MAH	NGAM-056-19-CA	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
54 Years	Female		91 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	NOT SPECIFIED					
ACYCLOVIR	Concomitant	NOT SPECIFIED					
CEFTRIAXONE SODIUM FOR INJECTION BP	Concomitant						
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	30.0 Gram	Total		Hypogammaglobulinaemia
SODIUM CHLORIDE	Concomitant	NOT SPECIFIED					
VALACYCLOVIR	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Acute pulmonary oedema	v.27.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Body temperature increased	v.27.1	
Chills	v.27.1	
Dyspnoea	v.27.1	
Hypoxia	v.27.1	
Tachycardia	v.27.1	
Tachypnoea	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000726191	0	2019-05-17	2019-05-17	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
38 Years	Male	168 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)
ALFACALCIDOL	Concomitant						
BETAMETHASONE	Concomitant	NOT SPECIFIED					
BISOPROLOL	Concomitant	Tablets					
CHOLECALCIFEROL	Concomitant	NOT SPECIFIED					
CLINDAMYCIN	Concomitant	NOT SPECIFIED					
CLONAZEPAM	Concomitant	Tablets					
CODEINE	Concomitant	Tablets					
DARBEPOETIN ALFA	Concomitant						
DICLOFENAC	Concomitant						
FOLIC ACID	Concomitant	NOT SPECIFIED					
FOSRENOL	Concomitant	TABLET (CHEWABLE)					
HYDROCORTISONE ACETATE CREAM USP	Concomitant	Cream					

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MAXITROL	Concomitant	NOT SPECIFIED					
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	27.0 Gram	8 every 1 Years		Infection prophylaxis
RANITIDINE	Concomitant	NOT SPECIFIED					
REPLAVITE	Concomitant	Tablets					
SENSIPAR	Concomitant	NOT SPECIFIED					
carbo	Concomitant	Capsules					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Alopecia	v.27.1	
Decreased activity	v.27.1	
Product substitution issue	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000726193	2	2019-05-21	2019-11-05	MAH	NGAM-077-19-CA	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
67 Years	Female		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)
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	30.0 Gram	Total		Immune thrombocytopenia
PREGABALIN	Concomitant	Capsules					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood pressure increased	v.27.1	
Chills	v.27.1	
Dyspnoea	v.27.1	
Ecchymosis	v.27.1	
Febrile nonhaemolytic transfusion reaction	v.27.1	
Haemolysis	v.27.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Oedema peripheral	v.27.1	
Pain in extremity	v.27.1	
Pyrexia	v.27.1	
Shock	v.27.1	
Tachycardia	v.27.1	
Tremor	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000726284	0	2019-05-22	2019-05-22	MAH	NGAM-067-19-CA	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)
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	30.0 Gram	Total		Leukaemia

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dyspnoea	v.27.1	
Hypersensitivity	v.27.1	
Oxygen saturation decreased	v.27.1	
Tremor	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000726513	0	2019-05-24	2019-05-24	MAH	NGAM-079-19-CA	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
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)
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	30.0 Gram	Total		Guillain-Barre syndrome

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood pressure increased	v.27.1	
Chills	v.27.1	
Oxygen saturation decreased	v.27.1	
Tachypnoea	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000727739	0	2019-07-02	2019-07-02	MAH	NGAM-099-19-CA	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
54 Years	Male	177 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)
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	40.0 Gram	1 every 4 Weeks		Hypogammaglobulinaemia

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Back pain	v.27.1	
Chills	v.27.1	
Pallor	v.27.1	
Peripheral coldness	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000727794	0	2019-07-03	2019-07-03	MAH	NGAM-105-19-CA	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
18 Years	Male		77 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	Intravenous (not otherwise specified)	150.0 Gram			Encephalitis autoimmune

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaemia	v.27.1	
Haemolysis	v.27.1	
Hepatic function abnormal	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000727857	1	2019-07-05	2019-08-18	MAH	NGAM-111-19-CA	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
31 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)
ACETAMINOPHEN	Concomitant	NOT SPECIFIED					
METOCLOPRAMIDE	Concomitant	NOT SPECIFIED					
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	60.0 Gram	1 every 1 Days	3.0 Days	Myasthenia gravis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.27.1	
Dizziness	v.27.1	
Erythema	v.27.1	
Headache	v.27.1	
Hypotension	v.27.1	
Myalgia	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000727963	2	2019-07-02	2020-03-10	MAH	NGAM-100-19-CA	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
28 Years	Male	165 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)
ACETAMINOPHEN	Concomitant	NOT SPECIFIED					
CETIRIZINE	Concomitant	Tablets					
COVERSYL	Suspect	Tablets	Oral	2.0 Milligram	1 every 1 Days		Product used for unknown indication
DIPHENHYDRAMINE	Concomitant	NOT SPECIFIED					
HYDROCORTISONE	Concomitant	NOT SPECIFIED					
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	25.0 Gram	1 every 1 Months		Hypogammaglobulinaemia

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Neurogenic shock	v.27.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Seizure	v.27.1	
Syncope	v.27.1	
Transfusion reaction	v.27.1	
Tremor	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
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Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000728494	0	2019-07-23	2019-07-23	MAH	NGAM-115-19-CA	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
64 Years	Female	150 Centimeter	68 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)
DEXAMETHASONE	Concomitant	NOT SPECIFIED					
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	35.0 Gram	1 every 1 Days	4.0 Days	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Ataxia	v.27.1	
Dizziness	v.27.1	
Hypoacusis	v.27.1	
Meningitis aseptic	v.27.1	
Salivary hypersecretion	v.27.1	
Vision blurred	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000728502	0	2019-07-23	2019-07-23	MAH	NGAM-116-19-CA	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
75 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)
ACETYLSALICYLIC ACID	Concomitant	NOT SPECIFIED					
CLAVULIN	Concomitant	NOT SPECIFIED					
DIPHENHYDRAMINE	Concomitant	NOT SPECIFIED					
FOLIC ACID	Concomitant	NOT SPECIFIED					
HYDROCORTISONE	Concomitant	NOT SPECIFIED					
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	30.0 Gram	1 every 1 Months		Hypogammaglobulinaemia

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.27.1	
Febrile nonhaemolytic transfusion reaction	v.27.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Feeling cold	v.27.1	
Hypertension	v.27.1	
Hypoaesthesia oral	v.27.1	
Malaise	v.27.1	
Pain in jaw	v.27.1	
Pyrexia	v.27.1	
Tachypnoea	v.27.1	
Tremor	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000729039	0	2019-08-07	2019-08-07	MAH	NGAM-125-19-CA	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	Male	174 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)
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	30.0 Gram	1 every 1 Days		Immune thrombocytopenia
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	30.0 Gram	1 every 1 Days		Immune thrombocytopenia

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.27.1	
Headache	v.27.1	
Vomiting	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000729076	1	2019-08-09	2019-10-28	MAH	NGAM-139-19-CA	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
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)
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	20.0 Milligram			Chronic inflammatory demyelinating polyradiculoneuropathy

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Erythema	v.27.1	
Pruritus	v.27.1	
Skin exfoliation	v.27.1	
Urticaria	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000729077	0	2019-08-09	2019-08-09	MAH	NGAM-127-19-CA	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
15 Years	Female		119 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					
CLINDAMYCIN	Concomitant	NOT SPECIFIED					
MEROPENEM	Concomitant	POWDER FOR SOLUTION INTRAVENOUS					
OXYGEN	Concomitant	Gas for inhalation					
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	50.0 Gram			Septic shock
VANCOMYCIN	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Acute pulmonary oedema	v.27.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dyspnoea	v.27.1	
Hypotension	v.27.1	
Tachycardia	v.27.1	
Tachypnoea	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000729082	2	2019-08-09	2020-02-12	MAH	NGAM-124-19-CA	Spontaneous	Physician

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
13 Years	Male		32 Kilogram	Fatal

Link / Duplicate Report Information

Record Type	Link AER** Number
Duplicate	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CEFAZOLIN	Concomitant						
CEFTRIAXONE FOR INJECTION USP	Concomitant	POWDER FOR SOLUTION INTRAMUSCULAR					
OXYGEN	Concomitant	Gas for inhalation					
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	30.0 Gram			Myocarditis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Acute respiratory distress syndrome	v.27.1	
Chills	v.27.1	
Dyspnoea	v.27.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Encephalopathy	v.27.1	
Hypertension	v.27.1	
Livedo reticularis	v.27.1	
Metabolic disorder	v.27.1	
Multiple organ dysfunction syndrome	v.27.1	
Pyrexia	v.27.1	
Tachycardia	v.27.1	
Tachypnoea	v.27.1	
Troponin increased	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000729208	0	2019-08-13	2019-08-13	MAH	NGAM-141-19-CA	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
48 Years	Male		70 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	Intravenous (not otherwise specified)	70.0 Gram			Immune thrombocytopenia

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.27.1	
Headache	v.27.1	
Meningitis aseptic	v.27.1	
Neck pain	v.27.1	
Pyrexia	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information

***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000729744	0	2019-08-30	2019-08-30	MAH	NGAM-156-19-CA	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
68 Years	Male		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)
CANDESARTAN	Concomitant						
LEVOTHYROXINE	Concomitant	NOT SPECIFIED					
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous drip	190.0 Gram	Total		Immune thrombocytopenia
PREDNISONE	Suspect	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaemia	v.27.1	
Coombs direct test positive	v.27.1	
Haemolysis	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000729770	0	2019-09-02	2019-09-02	MAH	NGAM-163-19-CA	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
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)
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	30.0 Gram			Leukaemia

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypotension	v.27.1	
Tachycardia	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000730414	0	2019-09-19	2019-09-19	MAH	NGAM-168-19-CA	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
8 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)
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	20.0 Gram			Chronic inflammatory demyelinating polyradiculoneuropathy

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypersensitivity	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000730420	0	2019-09-19	2019-09-19	MAH	NGAM-166-19-CA	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
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)
DEXTROSE	Concomitant	NOT SPECIFIED					
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	30.0 Gram			Chronic lymphocytic leukaemia

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypersensitivity	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000730584	0	2019-09-24	2019-09-24	MAH	NGAM-174-19-CA	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
88 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** 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	Intravenous drip	30.0 Gram	Total		Chronic inflammatory demyelinating polyradiculoneuropathy

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.27.1	
Chills	v.27.1	
Headache	v.27.1	
Hypertension	v.27.1	
Nausea	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000730593	0	2019-09-24	2019-09-24	MAH	NGAM-170-19-CA	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
65 Years	Male		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)
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	60.0 Gram	Total		Immune thrombocytopenia

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dyspnoea	v.27.1	
Hypertension	v.27.1	
Hypoxia	v.27.1	
Tachycardia	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000730596	2	2019-09-24	2019-10-28	MAH	NGAM-175-19-CA	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
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)
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	25.0 Gram	Total	115.0 Minutes	Chronic inflammatory demyelinating polyradiculoneuropathy

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.27.1	
Febrile nonhaemolytic transfusion reaction	v.27.1	
Headache	v.27.1	
Product contamination microbial	v.27.1	
Pyrexia	v.27.1	
Suspected transmission of an infectious agent via product	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000730795	0	2019-09-30	2019-09-30	MAH	NGAM-183-19-CA	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	Male	173 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)
ACETAMINOPHEN	Concomitant	NOT SPECIFIED					
FUROSEMIDE	Concomitant	NOT SPECIFIED					
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	20.0 Gram	Total		Autoimmune haemolytic anaemia
RED BLOOD CELLS	Suspect	NOT SPECIFIED	Unknown	1.0 Dosage forms			Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.27.1	
Dyspnoea	v.27.1	
Febrile nonhaemolytic transfusion reaction	v.27.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypertension	v.27.1	
Oxygen saturation decreased	v.27.1	
Pyrexia	v.27.1	
Tachycardia	v.27.1	
Tachypnoea	v.27.1	
Tremor	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000730989	0	2019-10-07	2019-10-07	MAH	NGAM-184-19-CA	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
78 Years	Female	158 Centimeter	44 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	Intravenous (not otherwise specified)	25.0 Gram		105.0 Minutes	Haemolytic anaemia

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.27.1	
Hyperhidrosis	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000731022	3	2019-10-07	2021-04-12	MAH	NGAM-181-19-CA	Spontaneous	Physician

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
76 Years	Female	158 Centimeter	65 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)
DIPHENHYDRAMINE	Concomitant	NOT SPECIFIED					
FOLIC ACID	Concomitant	NOT SPECIFIED					
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	60.0 Gram	Total		Bicytopenia
PLATELETS	Suspect	NOT SPECIFIED	Intravenous (not otherwise specified)	210.0 ml			Bicytopenia
PREDNISONE	Concomitant	NOT SPECIFIED					
PRIVIGEN	Suspect	SOLUTION INTRAVENOUS	Unknown				Bicytopenia

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.27.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Feeling cold	v.27.1	
Haemolysis	v.27.1	
Pyrexia	v.27.1	
Tachycardia	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000731026	1	2019-10-08	2019-10-29	MAH	NGAM-158-19-CA	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
83 Years	Male	96 Centimeter	96 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	NOT SPECIFIED					
CEFADROXIL	Concomitant	NOT SPECIFIED					
FAMOTIDINE	Concomitant	NOT SPECIFIED					
FENTANYL	Concomitant	NOT SPECIFIED					
FOLIC ACID	Concomitant	NOT SPECIFIED					
INSULIN	Concomitant	NOT SPECIFIED					
MAGNESIUM	Concomitant	NOT SPECIFIED					
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	40.0 Gram			Guillain-Barre syndrome
PROPOFOL	Concomitant						
RANITIDINE	Concomitant	NOT SPECIFIED					
ROCURONIUM	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bradycardia	v.27.1	
Hyperhidrosis	v.27.1	
Hypotension	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000732542	1	2019-11-05	2020-06-11	MAH	NGAM-197-19-CA	Spontaneous	Other health professional

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
69 Years	Male		81 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Duplicate	000731493

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AMOXICILLIN	Concomitant	NOT SPECIFIED					
AS-3 RBC LR (E7962V00)	Suspect		Intravenous (not otherwise specified)			145.0 Minutes	Neutropenia
MEROPENEM	Concomitant	POWDER FOR SOLUTION INTRAVENOUS					
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	30.0 Gram		2.0 Days	Non-Hodgkin's lymphoma

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain upper	v.27.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.27.1	
Dyspnoea	v.27.1	
Heart rate increased	v.27.1	
Pleuritic pain	v.27.1	
Pulmonary embolism	v.27.1	
Respiratory rate increased	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000732670	0	2019-11-06	2019-11-06	MAH	NGAM-200-19-CA	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
75 Years	Male		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)
NITROGLYCERIN	Concomitant	NOT SPECIFIED					
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	80.0 Gram	Total	95.0 Minutes	Immune thrombocytopenia

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Angina pectoris	v.27.1	
Chills	v.27.1	
Dyspnoea	v.27.1	
Febrile nonhaemolytic transfusion reaction	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000732922	0	2019-11-11	2019-11-11	MAH	NGAM-073-19-CA	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
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)
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	35.0 Gram			Myasthenia gravis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Acute pulmonary oedema	v.27.1	
Cough	v.27.1	
Dyspnoea	v.27.1	
Hyperhidrosis	v.27.1	
Hypertension	v.27.1	
Muscle spasms	v.27.1	
Stridor	v.27.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Tachycardia	v.27.1	
Tachypnoea	v.27.1	
Wheezing	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000732960	0	2019-11-14	2019-11-14	MAH	NGAM20619CA	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
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)
DARATUMUMAB	Concomitant	SOLUTION INTRAVENOUS					
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	35.0 Gram	Total		Plasma cell myeloma

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.27.1	
Dyspnoea	v.27.1	
Hypersensitivity	v.27.1	
Tremor	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000734289	0	2019-12-09	2019-12-09	MAH		Spontaneous	Other health professional

Serious report?	Death:	No	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	161 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)
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	160.0 Gram		2.0 Days	Guillain-Barre syndrome

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaemia	v.27.1	
Haemolysis	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000734798	0	2019-12-17	2019-12-17	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
39 Years	Male		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)
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	240.0 ml		35.0 Minutes	Immune thrombocytopenia
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	1.0 Gram		160.0 Minutes	Immune thrombocytopenia

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.27.1	
Feeling cold	v.27.1	
Headache	v.27.1	
Myalgia	v.27.1	
Pain	v.27.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Urticaria	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000735133	1	2019-12-18	2021-10-18	MAH		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	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** 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	Intravenous (not otherwise specified)	30.0 Gram	1 every 6 Weeks		Chronic inflammatory demyelinating polyradiculoneuropathy

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.27.1	
Hypertension	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000735439	0	2019-12-27	2019-12-27	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
72 Years	Male		82 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Duplicate	000919087

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	50.0 ml		45.0 Minutes	Guillain-Barre syndrome
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	300.0 ml		3.0 Hours	Guillain-Barre syndrome

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Febrile nonhaemolytic transfusion reaction	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000735562	0	2019-12-30	2019-12-30	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
72 Years	Female		70 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	Intravenous (not otherwise specified)	100.0 ml			Hypogammaglobulinaemia
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	200.0 ml			Hypogammaglobulinaemia
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	100.0 ml			Hypogammaglobulinaemia
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	200.0 ml			Hypogammaglobulinaemia

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Allergic transfusion reaction	v.27.1	64 Days
Pruritus	v.27.1	64 Days
Urticaria	v.27.1	64 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000737353	0	2020-01-16	2020-01-16	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
55 Years	Female	160 Centimeter	91 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)
CYTOSAR	Concomitant	POWDER FOR SOLUTION INTRATHECAL					
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)			50.0 Minutes	
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)			38.0 Minutes	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.27.1	
Blood pressure decreased	v.27.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.27.1	
Haemolysis	v.27.1	
Headache	v.27.1	
Nausea	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000908444	0	2020-01-31	2020-01-31	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
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)
PANZYGA	Suspect	SOLUTION INTRAVENOUS		250.0 ml		112.0 Minutes	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.27.1	
Hypertension	v.27.1	
Pyrexia	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000909637	0	2020-02-14	2020-02-14	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
78 Years	Male	159 Centimeter	70 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		100.0 ml		54.0 Minutes	Platelet count decreased
PANZYGA	Suspect	SOLUTION INTRAVENOUS		600.0 ml		4.0 Hours	Platelet count decreased

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.27.1	
Febrile nonhaemolytic transfusion reaction	v.27.1	
Hypertension	v.27.1	
Nausea	v.27.1	
Vomiting	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000910579	0	2020-02-21	2020-02-21	Hospital		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
15 Years	Male	175 Centimeter	87 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	000989072

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BIPHENTIN	Concomitant	CAPSULE, EXTENDED RELEASE					
DEXAMETHASONE	Concomitant	LIQUID INTRA-ARTICULAR					
PANZYGA	Suspect		Intravenous (not otherwise specified)	75.0 Gram			Thrombocytopenic purpura
PREDNISONE	Concomitant	NOT SPECIFIED					
RITUXAN	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cerebral venous sinus thrombosis	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000910798	1	2020-02-24	2020-03-19	MAH		Spontaneous	Physician

Serious report?	Death:	No	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)
PANZYGA	Suspect	SOLUTION INTRAVENOUS					Neonatal alloimmune thrombocytopenia
PANZYGA	Suspect	SOLUTION INTRAVENOUS					Neonatal alloimmune thrombocytopenia
PANZYGA	Suspect	SOLUTION INTRAVENOUS					Neonatal alloimmune thrombocytopenia
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)				Neonatal alloimmune thrombocytopenia

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Maternal exposure during pregnancy	v.27.1	
Treponema test positive	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000911183	0	2020-03-03	2020-03-03	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
6 Years	Female	110 Centimeter	19 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					
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	180.0 ml	Once	5.0 Hours	Epilepsy, CSWS syndrome, Attention deficit hyperactivity disorder

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.27.1	
Headache	v.27.1	
Nausea	v.27.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pyrexia	v.27.1	
Vomiting	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000911288	0	2020-02-21	2020-02-21	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
9 Years	Male		35 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					
CALCIUM CARBONATE	Concomitant	Tablets					
CHOLECALCIFEROL	Concomitant	NOT SPECIFIED					
FLUTICASONE	Concomitant	SPRAY, METERED DOSE					
HYDROCORTISONE	Concomitant	POWDER FOR SOLUTION INTRAMUSCULAR					
MONTELUKAST	Concomitant	NOT SPECIFIED					
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	20.0 Gram	1 every 1 Months		Hypogammaglobulinaemia

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.27.1	1 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000911638	0	2020-03-10	2020-03-10	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	120 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)
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	144.0 ml	1 every 1 Days	116.0 Minutes	Immune thrombocytopenia, Anaemia
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	200.0 ml	1 every 1 Days	117.0 Minutes	Immune thrombocytopenia, Anaemia

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood pressure increased	v.27.1	
Body temperature increased	v.27.1	
Chills	v.27.1	
Febrile nonhaemolytic transfusion reaction	v.27.1	
Heart rate increased	v.27.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Nausea	v.27.1	
Oxygen saturation increased	v.27.1	
Respiratory rate increased	v.27.1	
Vomiting	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000913092	0	2020-03-04	2020-03-04	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
7 Years	Male		22 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)
GABAPENTIN	Concomitant	Capsules					
IBUPROFEN	Concomitant	NOT SPECIFIED					
METHYLPREDNISOLONE NOS	Concomitant	NOT SPECIFIED					
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	2.5 Gram	Once		Myelitis
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	2.5 Gram	Once		Myelitis
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	10.0 Gram	Once		Myelitis

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	10.0 Gram	Once		Myelitis
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	10.0 Gram	Once		Myelitis
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	10.0 Gram	Once		Myelitis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.27.1	
Meningitis aseptic	v.27.1	2 Days
Nausea	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000913238	1	2020-04-01	2020-09-29	MAH		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			Unknown

Link / Duplicate Report Information

Record Type	Link AER** 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					
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	40.0 Gram	1 every 4 Weeks	26.0 Days	Secondary immunodeficiency
PSEUDOEPHEDRINE	Concomitant	NOT SPECIFIED					
RED BLOOD CELLS	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaemia	v.27.1	
Anti A antibody positive	v.27.1	
Asthenia	v.27.1	
Chills	v.27.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Crepitations	v.27.1	
Cyanosis	v.27.1	
Dyspnoea	v.27.1	
Febrile nonhaemolytic transfusion reaction	v.27.1	
Feeling cold	v.27.1	
Haemolysis	v.27.1	
Hypertension	v.27.1	
Nausea	v.27.1	
Pallor	v.27.1	
Pulmonary oedema	v.27.1	
Tachycardia	v.27.1	
Tachypnoea	v.27.1	
Tremor	v.27.1	
Wheezing	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000913443	0	2020-04-02	2020-04-02	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
53 Years	Female	163 Centimeter	53 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Duplicate	000932116

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	200.0 ml		130.0 Minutes	Thrombocytopenia, Immune thrombocytopenia, Hypersplenism
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	50.0 ml		37.0 Minutes	Thrombocytopenia, Immune thrombocytopenia, Hypersplenism

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain upper	v.27.1	
Back pain	v.27.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.27.1	
Febrile nonhaemolytic transfusion reaction	v.27.1	3 Days
Headache	v.27.1	
Nausea	v.27.1	
Pyrexia	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000915292	1	2020-04-23	2020-04-23	Hospital		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
56 Years	Female	180 Centimeter	118 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)
ANTIHISTAMINE ORAL PWR	Concomitant	Powder					
CORTICOSTEROID(S)	Concomitant	NOT SPECIFIED					
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	200.0 ml		90.0 Minutes	Immunodeficiency common variable
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	200.0 ml		60.0 Minutes	Immunodeficiency common variable

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood pressure increased	v.27.1	
Dysphonia	v.27.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dyspnoea	v.27.1	
Erythema	v.27.1	
Heart rate increased	v.27.1	
Hyperhidrosis	v.27.1	
Hypersensitivity	v.27.1	
Hypertension	v.27.1	
Pharyngeal oedema	v.27.1	
Stridor	v.27.1	
Throat tightness	v.27.1	
Use of accessory respiratory muscles	v.27.1	
Wheezing	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000922912	1	2020-07-29	2020-10-13	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	Female	161 Centimeter	41 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					
CETIRIZINE	Concomitant	Tablets					
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)			43.0 Minutes	Infection prophylaxis
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)			33.0 Minutes	Infection prophylaxis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Back pain	v.27.1	
Blood pressure increased	v.27.1	
Bradycardia	v.27.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.27.1	
Fatigue	v.27.1	
Febrile nonhaemolytic transfusion reaction	v.27.1	
Nausea	v.27.1	
Oxygen saturation decreased	v.27.1	
Oxygen therapy	v.27.1	
Product intolerance	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000924997	2	2020-09-01	2021-10-08	MAH		Spontaneous	Other 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
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)
OXYGEN	Concomitant	Gas for inhalation					
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	30.0 Gram	Total		Hypogammaglobulinaemia
PREDNISONE	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.27.1	
Chills	v.27.1	
Dyspnoea	v.27.1	
Headache	v.27.1	
Hypertension	v.27.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypoxia	v.27.1	
Pain in jaw	v.27.1	
Tachypnoea	v.27.1	
Transfusion-related acute lung injury	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000926151	0	2020-09-17	2020-09-17	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
49 Years	Female		66 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Duplicate	000943694

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	200.0 ml		3.0 Hours	
PANZYGA	Suspect	SOLUTION INTRAVENOUS		50.0 ml		74.0 Minutes	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.27.1	
Hypertension	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000927019	0	2020-09-28	2020-09-28	MAH		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
79 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)
ACETAMINOPHEN	Concomitant	NOT SPECIFIED					
CETIRIZINE	Concomitant	Tablets					
INSULIN	Concomitant	NOT SPECIFIED					
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	40.0 Gram	1 every 4 Weeks		Secondary immunodeficiency

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Acute pulmonary oedema	v.27.1	
Bronchospasm	v.27.1	
Chills	v.27.1	
Cyanosis	v.27.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dyspnoea	v.27.1	
Febrile nonhaemolytic transfusion reaction	v.27.1	
Hypertension	v.27.1	
Hypoaesthesia	v.27.1	
Tachycardia	v.27.1	
Tachypnoea	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000928557	0	2020-10-16	2020-10-16	MAH		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
7 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)
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	15.0 Gram		1.0 Days	Myelitis transverse

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.27.1	
Discomfort	v.27.1	
Meningitis aseptic	v.27.1	
Musculoskeletal stiffness	v.27.1	
Nausea	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000931283	0	2020-11-17	2020-11-17	MAH		Spontaneous	Nurse

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
14 Years	Male	140 Centimeter	30 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	Intravenous (not otherwise specified)	20.0 Gram			Immunodeficiency common variable

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.27.1	
Drug intolerance	v.27.1	
General physical health deterioration	v.27.1	
Headache	v.27.1	
Meningitis aseptic	v.27.1	
Nausea	v.27.1	
Pyrexia	v.27.1	
Vomiting	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000932116	1	2020-11-24	2021-03-05	MAH		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
53 Years	Female	163 Centimeter	53 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Duplicate	000913443
Duplicate	000914025

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	55.0 Gram			Immune thrombocytopenia

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain upper	v.27.1	
Back pain	v.27.1	
Chills	v.27.1	
Febrile nonhaemolytic transfusion reaction	v.27.1	
Feeling cold	v.27.1	
Headache	v.27.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Nausea	v.27.1	
Somnolence	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000936791	0	2021-01-22	2021-01-22	MAH		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
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)
CLINDAMYCIN	Concomitant	NOT SPECIFIED	Unknown				
DEXAMETHASONE	Concomitant	NOT SPECIFIED	Unknown				
MEROPENEM	Concomitant	POWDER FOR SOLUTION INTRAVENOUS					
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	80.0 Gram			Autoimmune haemolytic anaemia
RED BLOOD CELLS	Suspect	NOT SPECIFIED	Unknown				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Respiratory failure	v.27.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Tachypnoea	v.27.1	
Wheezing	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000942344	1	2021-03-10	2021-03-22	MAH		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
61 Years	Female		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)
FRAGMIN	Concomitant	SOLUTION INTRAVENOUS					
IRBESARTAN	Concomitant	Tablets	Unknown				
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	90.0 Gram	Total		Paraneoplastic syndrome
POLYETHYLENE GLYCOL	Concomitant	NOT SPECIFIED					
TAMSULOSIN	Concomitant	NOT SPECIFIED					
THIAMINE	Concomitant	Tablets					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaemia	v.27.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Angioedema	v.27.1	
Chest pain	v.27.1	
Drug intolerance	v.27.1	
Dyspnoea	v.27.1	
Nausea	v.27.1	
Platelet count decreased	v.27.1	
Swelling	v.27.1	
Tachycardia	v.27.1	
Vomiting	v.27.1	
Wheezing	v.27.1	
White blood cell count decreased	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000943694	2	2021-03-25	2021-12-22	MAH		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
49 Years	Female		66 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Duplicate	000926151
Duplicate	E2B_04443527

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	25.0 Gram		254.0 Minutes	Myasthenic syndrome
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	25.0 Gram		254.0 Minutes	Myasthenic syndrome

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.27.1	
Hypertension	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000944692	0	2021-04-06	2021-04-06	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
59 Years	Female	166 Centimeter	84 Kilogram	Recovering/resolving

Link / Duplicate Report Information

Record Type	Link AER** Number
Duplicate	E2B_04605968

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	50.0 Gram	1 every 1 Months		Immunodeficiency

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Back pain	v.27.1	
Chills	v.27.1	
Tremor	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000947626	0	2021-04-26	2021-04-26	MAH		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
66 Years	Female		57 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Duplicate	E2B_04605842

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
FLUTICASONE	Concomitant	NOT SPECIFIED					
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	30.0 Gram	1 every 1 Days	1.0 Days	Chronic inflammatory demyelinating polyradiculoneuropathy

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Epistaxis	v.27.1	
Haemolysis	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000949075	0	2021-05-06	2021-05-06	MAH		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
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)
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	20.0 Gram			Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Acute pulmonary oedema	v.27.1	
Dyspnoea	v.27.1	
Hypertension	v.27.1	
Tachypnoea	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000950358	1	2021-05-17	2021-09-30	Other		Spontaneous	Other health professional

Serious report?	Death:	No	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)
AS-3 RBC LR (E7962V00)	Suspect		Intravenous (not otherwise specified)			3.0 Hours	
PANZYGA	Suspect	SOLUTION INTRAVENOUS		150.0 ml		90.0 Minutes	
PLTA-1 LR IRR (E3056V00)	Suspect	NOT SPECIFIED	Intravenous (not otherwise specified)			100.0 Minutes	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Acute pulmonary oedema	v.27.1	
Blood culture negative	v.27.1	
Blood pressure increased	v.27.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dyspnoea	v.27.1	
Hypertension	v.27.1	
Hypervolaemia	v.27.1	
Hypoxia	v.27.1	
Oxygen saturation decreased	v.27.1	
Oxygen therapy	v.27.1	
Respiratory rate increased	v.27.1	
Tachycardia	v.27.1	
Wheezing	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000950469	0	2021-05-18	2021-05-18	MAH		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
63 Years	Female		82 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					
AMOXICILLIN/CLAVULANIC ACID	Concomitant	NOT SPECIFIED					
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	35.0 Gram	Cyclical	2.0 Days	Chronic inflammatory demyelinating polyradiculoneuropathy
triptan	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Back pain	v.27.1	
Drug ineffective	v.27.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.27.1	
Hot flush	v.27.1	
Nausea	v.27.1	
Oxygen saturation decreased	v.27.1	
Sleep apnoea syndrome	v.27.1	
Vomiting	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000953798	0	2021-06-09	2021-06-09	MAH		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
80 Years	Male		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)
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	50.0 Gram			Polymyositis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.27.1	
Dyspnoea	v.27.1	
Hypersensitivity	v.27.1	
Hypertension	v.27.1	
Wheezing	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000954890	0	2021-06-17	2021-06-17	MAH		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
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)
LIRAGLUTIDE	Concomitant						
PANZYGA	Suspect	SOLUTION INTRAVENOUS		50.0 Gram			Immunodeficiency

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.27.1	
Muscle spasms	v.27.1	
Nausea	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000954896	0	2021-06-17	2021-06-17	Hospital		Spontaneous	Other 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
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)
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	20.0 Gram	1 every 1 Months		
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	30.0 Gram	1 every 1 Months		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Meningitis aseptic	v.27.1	368 Days

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000960103	0	2021-07-22	2021-07-22	MAH		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
51 Years	Female		77 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	Intravenous (not otherwise specified)	80.0 Gram		142.0 Minutes	Chronic cutaneous lupus erythematosus

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.27.1	
Meningitis aseptic	v.27.1	
Nausea	v.27.1	
Vomiting	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000961132	0	2021-07-29	2021-07-29	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
72 Years	Male		118 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	Intravenous (not otherwise specified)	25.0 Gram	Once		Squamous cell carcinoma of skin, Pyrexia

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood pressure decreased	v.27.1	
Blood pressure increased	v.27.1	
Chills	v.27.1	
Cyanosis	v.27.1	
Heart rate increased	v.27.1	
Hypertension	v.27.1	
Oxygen saturation decreased	v.27.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Respiratory rate increased	v.27.1	
Tachycardia	v.27.1	1 Days
Transfusion reaction	v.27.1	
Transfusion-associated dyspnoea	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000963722	1	2021-08-18	2021-08-24	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
52 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)
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)				Secondary immunodeficiency

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.27.1	
Circulatory collapse	v.27.1	
Sepsis	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000965250	0	2021-08-27	2021-08-27	MAH		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
	Male		118 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	Intravenous (not otherwise specified)	25.0 Gram	Once		Immunodeficiency
PANZYGA	Suspect	SOLUTION INTRAVENOUS					Immunodeficiency

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.27.1	
Cyanosis	v.27.1	
Dyspnoea	v.27.1	
Hypertension	v.27.1	
Peripheral coldness	v.27.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Tachycardia	v.27.1	
Tachypnoea	v.27.1	
Wheezing	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000969403	3	2021-09-28	2021-12-21	MAH		Spontaneous	Other 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
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)
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	35.0 Gram		56.0 Minutes	Immune thrombocytopenia
PANZYGA	Suspect	SOLUTION INTRAVENOUS					Immune thrombocytopenia
PANZYGA	Suspect	SOLUTION INTRAVENOUS					Immune thrombocytopenia
PANZYGA	Suspect	SOLUTION INTRAVENOUS					Immune thrombocytopenia
PLATELETS	Suspect	NOT SPECIFIED					
RED BLOOD CELLS	Suspect	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.27.1	
Haemolysis	v.27.1	
Headache	v.27.1	
Hypertension	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000981444	0	2021-12-22	2021-12-22	MAH		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
77 Years	Male	172 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)
PANZYGA	Suspect	SOLUTION INTRAVENOUS					Immune thrombocytopenia
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	65.0 Gram			Immune thrombocytopenia

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaemia	v.27.1	
Haemolysis	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000982315	0	2022-01-03	2022-01-03	MAH		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
61 Years	Male		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)
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	30.0 Gram	Total		Immune thrombocytopenia
PREDNISONE	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.27.1	
Hyperhidrosis	v.27.1	
Hypersensitivity	v.27.1	
Hypotension	v.27.1	
Incorrect drug administration rate	v.27.1	
Syncope	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000982374	1	2022-01-04	2022-03-22	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
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)
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	70.0 Gram	1 every 1 Days	1.0 Days	Platelet count decreased

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaemia	v.27.1	
Anti A antibody positive	v.27.1	
Anti B antibody positive	v.27.1	
Haemolysis	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000989072	0	2022-02-22	2022-02-22	MAH		Other	Consumer/other non health professional

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
15 Years	Male	175 Centimeter	87 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	000910579

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
DEXAMETHASONE	Concomitant	Tablets					
METHYLPHENIDATE	Concomitant	NOT SPECIFIED					
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	75.0 Gram			Thrombocytopenic purpura
PREDNISONE	Concomitant	NOT SPECIFIED					
RITUXIMAB GP2013	Concomitant						

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cerebral venous sinus thrombosis	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000989412	0	2022-02-23	2022-02-23	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
9 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)
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	20.0 Gram	1 every 1 Months		Hypogammaglobulinaemia

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
001001084	1	2022-05-10	2022-06-15	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
83 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Duplicate	001053725

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	20.0 Gram	1 every 2 Days	80.0 Minutes	Immune thrombocytopenia
PLATELETS	Concomitant	NOT SPECIFIED				52.0 Minutes	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.27.1	
Electrocardiogram abnormal	v.27.1	
Hypertension	v.27.1	
Lung opacity	v.27.1	
Oxygen saturation decreased	v.27.1	
Tachycardia	v.27.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Tachypnoea	v.27.1	
Transfusion reaction	v.27.1	
Transfusion-associated dyspnoea	v.27.1	
Use of accessory respiratory muscles	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report 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.27.1	
Transfusion reaction	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
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.27.1	
Chills	v.27.1	
Dyspnoea	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
001030107	0	2022-12-21	2022-12-21	Hospital		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
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)
CALCIUM CARBONATE	Concomitant	NOT SPECIFIED					
PANTOPRAZOLE	Concomitant	POWDER FOR SOLUTION INTRAVENOUS					
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	5.0 ml		5.0 Minutes	Immune-mediated myositis
PREDNISONE	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.27.1	
Hypertension	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
001042372	0	2023-03-28	2023-03-28	MAH		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
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)
DIPHENHYDRAMINE	Concomitant	NOT SPECIFIED					
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	60.0 Gram		4.0 Hours	Immune thrombocytopenia

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.27.1	
Dyspnoea	v.27.1	
Hypersensitivity	v.27.1	
Pruritus	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2024-12-16 - 06:01:42 AM
Initial Received Date:	1965-01-01 to 2024-08-31
Latest Received Date:	N/A
Total Number of Reports:	173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
001048002	0	2023-05-16	2023-05-16	Hospital		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
69 Years				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	001070686

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	75.0 Gram	Once		Myositis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.27.1	
Troponin increased	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
001053725	0	2023-06-22	2023-06-22	MAH		Spontaneous	Other 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
83 Years	Male	164 Centimeter	87 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Duplicate	001001084

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	80.0 Gram	1 every 2 Days		Immune thrombocytopenia
PLATELETS	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.27.1	
Hypertension	v.27.1	
Tachycardia	v.27.1	
Transfusion reaction	v.27.1	
Transfusion-associated dyspnoea	v.27.1	
Use of accessory respiratory muscles	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
001055286	0	2023-07-05	2023-07-05	MAH		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
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)
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	10.0 Gram	Once		Secondary immunodeficiency

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
COVID-19	v.27.1	
Chills	v.27.1	
Dyspnoea	v.27.1	
Febrile nonhaemolytic transfusion reaction	v.27.1	
Hypertension	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-16 - 06:01:42 AM
Initial Received Date: 1965-01-01 to 2024-08-31
Latest Received Date: N/A
Total Number of Reports: 173 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
001070686	2	2023-11-08	2023-11-20	MAH		Spontaneous	Consumer/other non 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
69 Years				Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	001048002

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	75.0 Gram	Total		Myositis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.27.1	
Troponin increased	v.27.1	
Vasospasm	v.27.1	