Canada Vigilance

Summary of Reported Adverse Reactions

Report Information ***AER = Adverse Reaction Report

Adverse Reaction Report 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
Not Serious

Death		Disability		Congenital Anomaly	
Life Threatening		Hospitalization		Other Medically Important Conditions	

Patient Information

Age	Gender	Height	Weight	Report Outcome
43 Years	Female	164 Centimeter	59.7 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER Number
No duplicate or linked report	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 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	

Canada Vigilance

Summary of Reported Adverse Reactions

Report Information ***AER = Adverse Reaction Report

Adverse Reaction Report 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
Not Serious

Death		Disability		Congenital Anomaly	
Life Threatening		Hospitalization		Other Medically Important Conditions	

Patient Information

Age	Gender	Height	Weight	Report Outcome
65 Years	Female	158 Centimeter	56.8 Kilogram	Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PANZYGA	Concomitant	NOT SPECIFIED					
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	1000 mg/kg	1 every 1 Days		Immune thrombocytopenia
RED BLOOD CELLS	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	1000 mg/kg	1 every 1 Days		Immune thrombocytopenia

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	
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	

Canada Vigilance

Summary of Reported Adverse Reactions

Report Information ***AER = Adverse Reaction Report

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000698066	0	2017-06-06	2017-06-06	Hospital		Spontaneous	Physician

Serious Report
Not Serious

Death		Disability		Congenital Anomaly	
Life Threatening		Hospitalization		Other Medically Important Conditions	

Patient Information

Age	Gender	Height	Weight	Report Outcome
31 Years	Female	165 Centimeter	69.3 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER Number
No duplicate or linked report	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 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	

Canada Vigilance

Summary of Reported Adverse Reactions

Report Information ***AER = Adverse Reaction Report

Adverse Reaction Report 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
Serious

Death		Disability		Congenital Anomaly	
Life Threatening		Hospitalization	Yes	Other Medically Important Conditions	

Patient Information

Age	Gender	Height	Weight	Report Outcome
46 Years	Female	171 Centimeter	65.2 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER Number
No duplicate or linked report	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	NOT SPECIFIED					
CALCIUM	Concomitant	Tablets					
LORAZEPAM	Concomitant	NOT SPECIFIED					
METHOTREXATE	Concomitant	NOT SPECIFIED					
MULTIVITAMINE(S)	Concomitant	NOT SPECIFIED					
PANZYGA	Concomitant	NOT SPECIFIED					
PREDNISONE	Concomitant	NOT SPECIFIED					
SULFATRIM	Concomitant	NOT SPECIFIED					
VITAMIN D	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	70 Gram	2 every 1 Months		Dermatomyositis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration

Pruritus	v.27.1	
Urticaria	v.27.1	

Canada Vigilance

Summary of Reported Adverse Reactions

Report Information ***AER = Adverse Reaction Report

Adverse Reaction Report 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
Serious

Death		**Disability**		**Congenital Anomaly**	
Life Threatening		**Hospitalization**	Yes	**Other Medically Important Conditions**	

Patient Information

Age	Gender	Height	Weight	Report Outcome
46 Years	Female	171 Centimeter	65.2 Kilogram	Recovered/resolved

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACTONEL	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	60 Gram			Dermatomyositis
APO SULFATRIM TAB	Concomitant	NOT SPECIFIED					
CALCIUM	Concomitant	Tablets					
DIPHENHYDRAMINE HYDROCHLORIDE INJECTION USP	Concomitant	Tablets					
LORAZEPAM	Concomitant	NOT SPECIFIED					
MULTIVITAMINE(S)	Concomitant	LIQUID INTRAMUSCULAR					
OCTAGAM 10% FOR I.V. INFUSION	Concomitant	NOT SPECIFIED					
PANZYGA	Concomitant	NOT SPECIFIED					
PREDNISONE	Concomitant	NOT SPECIFIED					
VITAMIN D	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	10 Gram			Dermatomyositis

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 Information ***AER = Adverse Reaction Report

Adverse Reaction Report 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
Not Serious

Death		Disability		Congenital Anomaly	
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 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 Information ***AER = Adverse Reaction Report

Adverse Reaction Report 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
Not Serious

Death		Disability		Congenital Anomaly	
Life Threatening		Hospitalization		Other Medically Important Conditions	

Patient Information

Age	Gender	Height	Weight	Report Outcome
55 Years	Female	157.5 Centimeter	79.5 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 Gram	1 every 1 Days	2 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 Information ***AER = Adverse Reaction Report

Adverse Reaction Report 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
Not Serious

Death		Disability		Congenital Anomaly	
Life Threatening		Hospitalization		Other Medically Important Conditions	

Patient Information

Age	Gender	Height	Weight	Report Outcome
52 Years	Female	164 Centimeter	87.3 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER Number
No duplicate or linked report	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 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	
Vomiting	v.27.1	

Canada Vigilance

Summary of Reported Adverse Reactions

Report Information ***AER = Adverse Reaction Report

Adverse Reaction Report 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
Serious

Death		Disability		Congenital Anomaly	
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	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 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 Information ***AER = Adverse Reaction Report

Adverse Reaction Report 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
Not Serious

Death		Disability		Congenital Anomaly	
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	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 ml			Abscess drainage
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	127 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 Information ***AER = Adverse Reaction Report

Adverse Reaction Report 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
Serious

Death		Disability		Congenital Anomaly	
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	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 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 Information ***AER = Adverse Reaction Report

Adverse Reaction Report 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
Serious

Death		Disability		Congenital Anomaly	
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	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 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 Information ***AER = Adverse Reaction Report

Adverse Reaction Report 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
Serious

Death		Disability		Congenital Anomaly	
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 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 Information ***AER = Adverse Reaction Report

Adverse Reaction Report 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
Not Serious

Death		Disability		Congenital Anomaly	
Life Threatening		Hospitalization		Other Medically Important Conditions	

Patient Information

Age	Gender	Height	Weight	Report Outcome
30 Years	Female	147.5 Centimeter	46.51 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 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 Information ***AER = Adverse Reaction Report

Adverse Reaction Report 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
Not Serious

Death		Disability		Congenital Anomaly	
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	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 Gram	1 every 3 Weeks	75 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 Information ***AER = Adverse Reaction Report

Adverse Reaction Report 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
Not Serious

Death		Disability		Congenital Anomaly	
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	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 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 Information ***AER = Adverse Reaction Report

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000708592	0	2018-01-30	2018-01-30	Hospital		Spontaneous	Other health professional

Serious Report
Serious

Death		Disability		Congenital Anomaly	
Life Threatening		Hospitalization		Other Medically Important Conditions	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
66 Years	Male		70 Kilogram	Recovered/resolved

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PANZYGA ALSO KNOW AS IMMUNE GLOBULIN (HUMAN)	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	70 Gram	1 every 1 Months		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.27.1	
Anxiety	v.27.1	
Dyspnoea	v.27.1	
Flushing	v.27.1	
Pruritus	v.27.1	
Restlessness	v.27.1	
Transfusion reaction	v.27.1	

Urticaria	v.27.1	

Canada Vigilance

Summary of Reported Adverse Reactions

Report Information ***AER = Adverse Reaction Report

Adverse Reaction Report 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
Not Serious

Death		Disability		Congenital Anomaly	
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	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 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 Information ***AER = Adverse Reaction Report

Adverse Reaction Report 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
Not Serious

Death		Disability		Congenital Anomaly	
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	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	Capsules					
BENADRYL	Concomitant	Tablets					
GRAVOL	Concomitant	Tablets					
NAPROXEN	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	300 ml	Once		
PANZYGA	Concomitant	NOT SPECIFIED					
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	300 ml	Once		
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	100 ml	Once		
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	300 ml	Once		
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	300 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 Information ***AER = Adverse Reaction Report

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000714629	0	2018-06-17	2018-06-17	Hospital		Spontaneous	Other health professional

Serious Report
Serious

Death		Disability		Congenital Anomaly	
Life Threatening		Hospitalization		Other Medically Important Conditions	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
29 Years	Male			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
LOSARTAN	Concomitant	Tablets					
PANZYGA ALSO KNOW AS IMMUNE GLOBULIN (HUMAN)	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	20 Gram	1 every 1 Days		

Adverse Reaction Term Information

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

Canada Vigilance

Summary of Reported Adverse Reactions

Report Information ***AER = Adverse Reaction Report

Adverse Reaction Report 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
Serious

Death		Disability		Congenital Anomaly	
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 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 Information ***AER = Adverse Reaction Report

Adverse Reaction Report 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
Serious

Death		Disability	Yes	Congenital Anomaly	
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	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	NOT SPECIFIED					
BETAMETHASONE	Concomitant	NOT SPECIFIED					
BISOPROLOL	Concomitant	Tablets					
CHOLECALCIFEROL	Concomitant						
CLINDAMYCIN	Concomitant	Tablets					
CLONAZEPAM	Concomitant	NOT SPECIFIED					
CODEINE	Concomitant	NOT SPECIFIED					
DARBEPOETIN ALFA	Concomitant	Tablets					
DICLOFENAC	Concomitant	Capsules					
FOLIC ACID	Concomitant						
FOSRENOL	Concomitant	Cream					
HYDROCORTISONE ACETATE CREAM USP	Concomitant						

MAXITROL	Concomitant	Tablets					
PANZYGA	Concomitant	NOT SPECIFIED					
RANITIDINE	Concomitant	NOT SPECIFIED					
REPLAVITE	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	27 Gram	8 every 1 Years		Infection prophylaxis
SENSIPAR	Concomitant	NOT SPECIFIED					
carbo	Concomitant	TABLET (CHEWABLE)					

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 Information ***AER = Adverse Reaction Report

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000731493	0	2019-10-21	2019-10-21	Other	RPEXP09960/MED02643	Spontaneous	Other health professional

Serious Report
Serious

Death		Disability		Congenital Anomaly	
Life Threatening	Yes	Hospitalization	Yes	Other Medically Important Conditions	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
69 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER Number
Duplicate	000732542

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)				Neutropenia
PANZYGA ALSO KNOW AS IMMUNE GLOBULIN (HUMAN)	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	80 ml			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain upper	v.27.1	
Blood pressure decreased	v.27.1	
Body temperature decreased	v.27.1	
Chest pain	v.27.1	
Culture wound positive	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	
Staphylococcus test positive	v.27.1	
Ventilation/perfusion scan	v.27.1	

Canada Vigilance

Summary of Reported Adverse Reactions

Report Information ***AER = Adverse Reaction Report

Adverse Reaction Report 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
Not Serious

Death	No	**Disability**	No	**Congenital Anomaly**	No
Life Threatening	No	**Hospitalization**	No	**Other Medically Important Conditions**	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
39 Years	Male		90 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER Number
No duplicate or linked report	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 ml		35 Minutes	Immune thrombocytopenia
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	1 Gram		160 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	
Urticaria	v.27.1	

Canada Vigilance

Summary of Reported Adverse Reactions

Report Information ***AER = Adverse Reaction Report

Adverse Reaction Report 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
Serious

Death	No	**Disability**	No	**Congenital Anomaly**	No
Life Threatening	No	**Hospitalization**	No	**Other Medically Important Conditions**	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
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)	300 ml		3 Hours	Guillain-Barre syndrome
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	50 ml		45 Minutes	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 Information ***AER = Adverse Reaction Report

Adverse Reaction Report 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
Not Serious

Death	No	Disability	No	Congenital Anomaly	No
Life Threatening	No	Hospitalization	No	Other Medically Important Conditions	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
72 Years	Female		70 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER Number
No duplicate or linked report	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 ml			Hypogammaglobulinaemia
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	200 ml			Hypogammaglobulinaemia
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	100 ml			Hypogammaglobulinaemia
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	200 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 Information ***AER = Adverse Reaction Report

Adverse Reaction Report 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
Serious

Death	No	**Disability**	No	**Congenital Anomaly**	No
Life Threatening	No	**Hospitalization**	No	**Other Medically Important Conditions**	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
55 Years	Female	160 Centimeter	91 Kilogram	Recovered/resolved

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CYTOSAR	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)			50 Minutes	
PANZYGA	Concomitant	POWDER FOR SOLUTION INTRATHECAL					
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)			38 Minutes	

Adverse Reaction Term Information

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

Nausea	v.27.1	

Canada Vigilance

Summary of Reported Adverse Reactions

Report Information ***AER = Adverse Reaction Report

Adverse Reaction Report 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
Not Serious

Death	No	**Disability**	No	**Congenital Anomaly**	No
Life Threatening	No	**Hospitalization**	No	**Other Medically Important Conditions**	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
67 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER Number
No duplicate or linked report	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 ml		112 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 Information ***AER = Adverse Reaction Report

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000908466	0	2020-02-05	2020-02-05	Hospital		Spontaneous	Other health professional

Serious Report
Serious

Death	No	**Disability**	No	**Congenital Anomaly**	No
Life Threatening	No	**Hospitalization**	No	**Other Medically Important Conditions**	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
				Recovered/resolved

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PANZYGA ALSO KNOW AS IMMUNE GLOBULIN (HUMAN)	Suspect	SOLUTION INTRAVENOUS				140 Minutes	Immunodeficiency

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.27.1	
Headache	v.27.1	
Nausea	v.27.1	
Pain	v.27.1	
Pyrexia	v.27.1	
Transfusion reaction	v.27.1	
Vomiting	v.27.1	

Canada Vigilance

Summary of Reported Adverse Reactions

Report Information ***AER = Adverse Reaction Report

Adverse Reaction Report 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
Serious

Death	No	**Disability**	No	**Congenital Anomaly**	No
Life Threatening	No	**Hospitalization**	No	**Other Medically Important Conditions**	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
78 Years	Male	159 Centimeter	70 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER Number
No duplicate or linked report	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		600 ml		4 Hours	Platelet count decreased
PANZYGA	Suspect	SOLUTION INTRAVENOUS		100 ml		54 Minutes	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 Information ***AER = Adverse Reaction Report

Adverse Reaction Report 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
Serious

Death	No	**Disability**	No	**Congenital Anomaly**	No
Life Threatening	Yes	**Hospitalization**	Yes	**Other Medically Important Conditions**	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
15 Years	Male	175 Centimeter	87.9 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	LIQUID INTRA-ARTICULAR					
DEXAMETHASONE	Concomitant	NOT SPECIFIED					
PANZYGA	Concomitant						
PREDNISONE	Suspect		Intravenous (not otherwise specified)	75 Gram			Thrombocytopenic purpura
RITUXAN	Concomitant	CAPSULE					
		EXTENDED RELEASE					

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 Information ***AER = Adverse Reaction Report

Adverse Reaction Report 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
Serious

Death	No	**Disability**	No	**Congenital Anomaly**	No
Life Threatening	No	**Hospitalization**	No	**Other Medically Important Conditions**	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
6 Years	Female	110 Centimeter	19 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER Number
No duplicate or linked report	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	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	180 ml	Once	5 Hours	Attention deficit hyperactivity disorder
PANZYGA	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

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

Canada Vigilance

Summary of Reported Adverse Reactions

Report Information ***AER = Adverse Reaction Report

Adverse Reaction Report 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
Serious

Death	No	**Disability**	No	**Congenital Anomaly**	No
Life Threatening	No	**Hospitalization**	Yes	**Other Medically Important Conditions**	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
9 Years	Male		35.5 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER Number
No duplicate or linked report	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	SPRAY					
FLUTICASONE	Concomitant	METERED DOSE					
HYDROCORTISONE	Concomitant	NOT SPECIFIED					
MONTELUKAST	Suspect	NOT SPECIFIED	Intravenous (not otherwise specified)	20 Gram	1 every 1 Months		Hypogammaglobulinaemia
PANZYGA	Concomitant	SOLUTION INTRAVENOUS					
		POWDER FOR SOLUTION INTRAMUSCULAR					

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 Information ***AER = Adverse Reaction Report

Adverse Reaction Report 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
Serious

Death	No	**Disability**	No	**Congenital Anomaly**	No
Life Threatening	No	**Hospitalization**	No	**Other Medically Important Conditions**	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
70 Years	Male	120 Centimeter		Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER Number
No duplicate or linked report	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 ml	1 every 1 Days	117 Minutes	Immune thrombocytopenia
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	144 ml	1 every 1 Days	116 Minutes	Immune thrombocytopenia

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	
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 Information ***AER = Adverse Reaction Report

Adverse Reaction Report 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
Serious

Death	No	**Disability**	No	**Congenital Anomaly**	No
Life Threatening	No	**Hospitalization**	Yes	**Other Medically Important Conditions**	No

Patient Information

Age	Gender	Height	Weight	Report Outcome
7 Years	Male		22.8 Kilogram	Recovered/resolved

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
GABAPENTIN	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	10 Gram	Once		Myelitis
IBUPROFEN	Concomitant	NOT SPECIFIED					
METHYLPREDNISOLONE NOS	Concomitant	NOT SPECIFIED					
PANZYGA	Concomitant	Capsules					
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	10 Gram	Once		Myelitis
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	10 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 Gram	Once		Myelitis

PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	2.5 Gram	Once		Myelitis

Adverse Reaction Term Information

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

Canada Vigilance

Summary of Reported Adverse Reactions

Report Information ***AER = Adverse Reaction Report

Adverse Reaction Report 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
Serious

Death	No	**Disability**	No	**Congenital Anomaly**	No
Life Threatening	No	**Hospitalization**	No	**Other Medically Important Conditions**	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
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 ml		130 Minutes	Thrombocytopenia
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	50 ml		37 Minutes	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	
Headache	v.27.1	
Nausea	v.27.1	

Pyrexia	v.27.1	3 Days

Canada Vigilance

Summary of Reported Adverse Reactions

Report Information ***AER = Adverse Reaction Report

Adverse Reaction Report 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
Serious

Death	No	**Disability**	No	**Congenital Anomaly**	No
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	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 ml		60 Minutes	Immunodeficiency common variable
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	200 ml		90 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	
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 Information ***AER = Adverse Reaction Report

Adverse Reaction Report 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
Serious

Death	No	**Disability**	No	**Congenital Anomaly**	No
Life Threatening	No	**Hospitalization**	No	**Other Medically Important Conditions**	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
70 Years	Female	161 Centimeter	41 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER Number
No duplicate or linked report	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 Minutes	Infection prophylaxis
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)			33 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	
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 Information ***AER = Adverse Reaction Report

Adverse Reaction Report 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
Serious

Death	No	Disability	No	Congenital Anomaly	No
Life Threatening	No	Hospitalization	No	Other Medically Important Conditions	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
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 ml		3 Hours	
PANZYGA	Suspect	SOLUTION INTRAVENOUS		50 ml		74 Minutes	

Adverse Reaction Term Information

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

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Summary of Reported Adverse Reactions

Report Information ***AER = Adverse Reaction Report

Adverse Reaction Report 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
Serious

Death	No	**Disability**	No	**Congenital Anomaly**	No
Life Threatening	No	**Hospitalization**	No	**Other Medically Important Conditions**	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
59 Years	Female	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 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	

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Summary of Reported Adverse Reactions

Report Information ***AER = Adverse Reaction Report

Adverse Reaction Report 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
Serious

Death	No	**Disability**	No	**Congenital Anomaly**	No
Life Threatening	No	**Hospitalization**	No	**Other Medically Important Conditions**	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
94 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER Number
No duplicate or linked report	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	SOLUTION INTRAVENOUS		150 ml		90 Minutes	
PANZYGA	Suspect	NOT SPECIFIED	Intravenous (not otherwise specified)			100 Minutes	
PLTA-1 LR IRR (E3056V00)	Suspect		Intravenous (not otherwise specified)			3 Hours	

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	
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	

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Summary of Reported Adverse Reactions

Report Information ***AER = Adverse Reaction Report

Adverse Reaction Report 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
Serious

Death		**Disability**		**Congenital Anomaly**	
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	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 Gram	1 every 1 Months		
PANZYGA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	30 Gram	1 every 1 Months		

Adverse Reaction Term Information

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

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Summary of Reported Adverse Reactions

Report Information ***AER = Adverse Reaction Report

Adverse Reaction Report 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
Serious

Death	No	**Disability**	No	**Congenital Anomaly**	No
Life Threatening	No	**Hospitalization**	No	**Other Medically Important Conditions**	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
72 Years	Male		118 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER Number
No duplicate or linked report	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 Gram	Once		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	
Respiratory rate increased	v.27.1	

Tachycardia	v.27.1	1 Days
Transfusion reaction	v.27.1	
Transfusion-associated dyspnoea	v.27.1	

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Summary of Reported Adverse Reactions

Report Information ***AER = Adverse Reaction Report

Adverse Reaction Report 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
Serious

Death		Disability		Congenital Anomaly	
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	Concomitant	NOT SPECIFIED				52 Minutes	
PLATELETS	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	20 Gram	1 every 2 Days	80 Minutes	Immune thrombocytopenia

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	
Tachypnoea	v.27.1	

Transfusion reaction	v.27.1	
Transfusion-associated dyspnoea	v.27.1	
Use of accessory respiratory muscles	v.27.1	

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Summary of Reported Adverse Reactions

Report Information ***AER = Adverse Reaction Report

Adverse Reaction Report 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
Serious

Death	No	**Disability**	No	**Congenital Anomaly**	No
Life Threatening	No	**Hospitalization**	No	**Other Medically Important Conditions**	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
48 Years	Male	181 Centimeter	81 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER Number
No duplicate or linked report	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 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	

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Summary of Reported Adverse Reactions

Report Information ***AER = Adverse Reaction Report

Adverse Reaction Report 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
Serious

Death	No	**Disability**	No	**Congenital Anomaly**	No
Life Threatening	No	**Hospitalization**	No	**Other Medically Important Conditions**	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
86 Years	Female	153 Centimeter	50 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER Number
No duplicate or linked report	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 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	

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Summary of Reported Adverse Reactions

Report Information ***AER = Adverse Reaction Report

Adverse Reaction Report 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
Serious

Death	No	**Disability**	No	**Congenital Anomaly**	No
Life Threatening	Yes	**Hospitalization**	No	**Other Medically Important Conditions**	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
67 Years	Female	152 Centimeter	56 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER Number
No duplicate or linked report	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	POWDER FOR SOLUTION INTRAVENOUS					
PANTOPRAZOLE	Concomitant	NOT SPECIFIED					
PANZYGA	Concomitant	NOT SPECIFIED					
PREDNISONE	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	5 ml		5 Minutes	Immune-mediated myositis

Adverse Reaction Term Information

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

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Summary of Reported Adverse Reactions

Report Information ***AER = Adverse Reaction Report

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
001036090	0	2023-02-09	2023-02-09	Hospital		Spontaneous	Other health professional

Serious Report
Serious

Death		Disability		Congenital Anomaly	
Life Threatening	Yes	Hospitalization		Other Medically Important Conditions	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
67 Years	Female	152 Centimeter	56 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER Number
No duplicate or linked report	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	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	5 ml		5 Minutes	Myositis
PANZYGA ALSO KNOW AS IMMUNE GLOBULIN (HUMAN)	Concomitant	NOT SPECIFIED					
PREDNISONE	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood pressure increased	v.27.1	
Breath sounds abnormal	v.27.1	
Dyspnoea	v.27.1	
Fear of death	v.27.1	

Flushing	v.27.1	
Heart rate increased	v.27.1	
Hypersensitivity	v.27.1	
Hypotension	v.27.1	
Hypoxia	v.27.1	
Oxygen saturation decreased	v.27.1	
Respiratory rate decreased	v.27.1	
Tachycardia	v.27.1	
Transfusion reaction	v.27.1	

Canada Vigilance

Summary of Reported Adverse Reactions

Report Information ***AER = Adverse Reaction Report

Adverse Reaction Report 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
Serious

Death	No	**Disability**	No	**Congenital Anomaly**	No
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 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	