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
000585940	0	2014-02-04	2014-02-04	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
	Female		9.94 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)
BENADRYL	Concomitant	NOT SPECIFIED					
OCTAGAM 10% FOR I.V. INFUSION	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	20 Gram		2 Days	Kawasaki's disease
TYLENOL	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Coombs direct test positive	v.27.1	
Haemoglobin decreased	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
000600701	0	2014-04-10	2014-04-10	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
70 Years	Female		60 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)
OCTAGAM 10% FOR I.V. INFUSION	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	20 Gram	3 every 1 Months	2 Days	Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.27.1	
Swelling face	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
000603927	0	2014-04-25	2014-04-25	Community		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
39 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER Number
Duplicate	000636746

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
OCTAGAM 10% FOR I.V. INFUSION	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	20 Gram	Once		Myositis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Haemolysis	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
000623275	1	2014-08-28	2014-09-19	Hospital		Spontaneous	Physician

Serious Report
Serious

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
25 Years	Female	69 Inch	78.9 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER Number
Duplicate	000627727

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
HYDROXYCHLOROQUINE	Concomitant	NOT SPECIFIED					
METHYLPREDNISOLONE SODIUM SUCCINATE FOR INJECTION	Concomitant	Tablets					
METHYLPREDNISOLONE SODIUM SUCCINATE FOR INJECTION	Concomitant	NOT SPECIFIED					
MYCOPHENOLATE MOFETIL	Concomitant	NOT SPECIFIED					
OCTAGAM 10% FOR I.V. INFUSION	Concomitant	NOT SPECIFIED					
RED BLOOD CELLS	Concomitant	NOT SPECIFIED					
SEPTRA	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	90 Gram	1 every 1 Days	2 Days	Thrombocytopenia

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anti-erythrocyte antibody positive	v.27.1	
Condition aggravated	v.27.1	
Haemolysis	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
000626054	0	2014-09-17	2014-09-17	Community		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	Female		65 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)
OCTAGAM 10% FOR I.V. INFUSION	Suspect	SOLUTION INTRAVENOUS	Unknown	30 Gram	1 every 1 Days	3 Days	Myasthenia gravis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood lactate dehydrogenase increased	v.27.1	
Chromaturia	v.27.1	
Haemoglobin decreased	v.27.1	
Reticulocyte count increased	v.27.1	
Urine viscosity 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
000629594	0	2014-10-22	2014-10-22	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
30 Years	Male		61.1 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER Number
Duplicate	000640417

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
HEPARIN SODIUM	Concomitant	NOT SPECIFIED					
L-THYROXINE	Concomitant	NOT SPECIFIED					
OCTAGAM 10% FOR I.V. INFUSION	Concomitant	SOLUTION INTRAVENOUS					
OCTAGAM 10% FOR I.V. INFUSION	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	60 Gram	1 every 1 Days	2 Days	Dermatomyositis
SEPTRA INJECTION	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	60 Gram	1 every 1 Days	2 Days	Dermatomyositis
SOLU-MEDROL	Concomitant	SOLUTION INTRAVENOUS					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaemia	v.27.1	
Anti-erythrocyte antibody positive	v.27.1	

Coombs direct test positive	v.27.1	
Haemoglobin decreased	v.27.1	
Haemolysis	v.27.1	
Red blood cell spherocytes present	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
000635286	0	2014-12-08	2014-12-08	Community		Spontaneous	Consumer/other non 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
53 Years	Female	165 Centimeter	112 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)
OCTAGAM 10% FOR I.V. INFUSION	Suspect		Unknown	20 Gram			Chronic inflammatory demyelinating polyradiculoneuropathy
OCTAGAM 10% FOR I.V. INFUSION	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	65 Gram	Total		Chronic inflammatory demyelinating polyradiculoneuropathy
OCTAGAM 10% FOR I.V. INFUSION	Suspect		Unknown	5 Gram			Chronic inflammatory demyelinating polyradiculoneuropathy
OCTAGAM 10% FOR I.V. INFUSION	Suspect		Unknown	20 Gram			Chronic inflammatory demyelinating polyradiculoneuropathy
OCTAGAM 10% FOR I.V. INFUSION	Suspect		Unknown	20 Gram			Chronic inflammatory demyelinating polyradiculoneuropathy

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Flushing	v.27.1	1 Days
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
000638099	0	2015-01-08	2015-01-08	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
9 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)
BENADRYL	Concomitant	NOT SPECIFIED					
HYDROCORTISONE	Concomitant	NOT SPECIFIED					
OCTAGAM 10% FOR I.V. INFUSION	Concomitant	NOT SPECIFIED					
OCTAGAM 10% FOR I.V. INFUSION	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	600 ml	Total		Hypothalamo-pituitary disorder
OCTAGAM 10% FOR I.V. INFUSION	Suspect		Intravenous (not otherwise specified)	200 ml			Hypothalamo-pituitary disorder
TYLENOL	Suspect		Intravenous (not otherwise specified)	200 ml			Hypothalamo-pituitary disorder

Adverse Reaction Term Information

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

Hypersensitivity	v.27.1	
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
000638106	0	2015-01-08	2015-01-08	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
9 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER Number
Duplicate	000660013

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BENADRYL	Concomitant	NOT SPECIFIED					
HYDROCORTISONE	Concomitant	Injection					
OCTAGAM 10% FOR I.V. INFUSION	Concomitant	Tablets					
TYLENOL	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	190 ml	Total		Urinary tract infection

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypoxia	v.27.1	
Transfusion-related circulatory overload	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
000639422	0	2015-01-14	2015-01-14	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
7 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)
OCTAGAM 10% FOR I.V. INFUSION	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	20 Gram	Once		Kawasaki's disease

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Coombs direct test positive	v.27.1	
Flushing	v.27.1	
Pyrexia	v.27.1	
Tachycardia	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
000641716	0	2015-02-04	2015-02-04	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
54 Years	Female	166 Centimeter	112 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)
OCTAGAM 10% FOR I.V. INFUSION	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	25 Gram	Total		Chronic inflammatory demyelinating polyradiculoneuropathy

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Erythema	v.27.1	
Flushing	v.27.1	
Gait disturbance	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
000642876	0	2015-02-17	2015-02-17	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
7 Years	Male		35 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER Number
Duplicate	000660008

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ADVIL	Concomitant	NOT SPECIFIED					
BENADRYL	Concomitant	NOT SPECIFIED					
OCTAGAM 10% FOR I.V. INFUSION	Suspect		Intravenous (not otherwise specified)	35 Gram	Once		Nervous system disorder
OCTAGAM 10% FOR I.V. INFUSION	Concomitant	NOT SPECIFIED					
TYLENOL	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	35 Gram	1 every 1 Days	2 Days	Nervous system disorder

Adverse Reaction Term Information

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

Headache	v.27.1	
Musculoskeletal stiffness	v.27.1	
Nausea	v.27.1	
Photophobia	v.27.1	
Pyrexia	v.27.1	
Vomiting projectile	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
000643416	0	2015-02-23	2015-02-23	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
55 Years	Female	165 Centimeter	77 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)
LEVOFLOXACIN	Concomitant	NOT SPECIFIED					
OCTAGAM 10% FOR I.V. INFUSION	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	40 Gram	Total		Immunodeficiency common variable

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dermatitis contact	v.27.1	
Hypersensitivity	v.27.1	
Transfusion reaction	v.27.1	
Urticaria	v.27.1	
Vulvovaginal pruritus	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
000643580	0	2015-02-24	2015-02-24	Community		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
22 Years	Male	164.5 Centimeter	79.5 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)
AMOXICILLIN	Concomitant	NOT SPECIFIED					
CLAVULIN	Concomitant	NOT SPECIFIED					
DOXYCYCLINE	Concomitant	NOT SPECIFIED					
OCTAGAM 10% FOR I.V. INFUSION	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	45 Gram	Total		Hypogammaglobulinaemia

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Erythema	v.27.1	30 Minutes
Hypersensitivity	v.27.1	30 Minutes
Peripheral swelling	v.27.1	30 Minutes

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
000646419	0	2015-03-12	2015-03-12	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
85 Years	Male	166 Centimeter	73 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER Number
Duplicate	000650447

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETAMINOPHEN	Concomitant	NOT SPECIFIED					
CANDESARTAN CILEXETIL	Concomitant	NOT SPECIFIED					
DOCUSATE SODIUM	Concomitant	Tablets					
FRAGMIN	Concomitant	SOLUTION INTRAVENOUS					
FUROSEMIDE	Concomitant	NOT SPECIFIED					
GABAPENTIN	Concomitant	POWDER FOR SOLUTION INTRAVENOUS					
HALDOL	Concomitant	NOT SPECIFIED					
NIFEDIPINE	Concomitant	NOT SPECIFIED					
OCTAGAM 10% FOR I.V. INFUSION	Concomitant	NOT SPECIFIED					
PANTOPRAZOLE	Concomitant	Powder					
POTASSIUM CHLORIDE	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	65 Gram	Total	1 Days	Acquired Von Willebrand's disease

SYMBICORT TURBUHALER	Concomitant	Capsules					
VITAMIN B12	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypersensitivity	v.27.1	
Hypoxia	v.27.1	
Oxygen therapy	v.27.1	4 Days
Rash papular	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
000652548	0	2015-05-07	2015-05-07	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
37 Years	Female	163 Centimeter	72 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)
LEVOTHYROXINE	Concomitant	NOT SPECIFIED					
OCTAGAM 10% FOR I.V. INFUSION	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	10 Gram	Total		Immunodeficiency common variable

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Flushing	v.27.1	
Pyrexia	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
000655638	0	2015-06-02	2015-06-02	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
91 Years	Male	166.5 Centimeter	75 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER Number
Duplicate	000657771

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ATORVASTATIN CALCIUM	Concomitant	NOT SPECIFIED					
BISOPROLOL	Concomitant	Tablets					
ELIQUIS FILM-COATED	Concomitant	Tablets					
FUROSEMIDE	Concomitant	Tablets					
HYDROMORPHONE	Concomitant	NOT SPECIFIED					
MELATONIN	Concomitant	Tablets					
METFORMIN	Concomitant	NOT SPECIFIED					
OCTAGAM 10% FOR I.V. INFUSION	Concomitant	NOT SPECIFIED					
PANTOLOC	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	30 Gram	Total		Product used for unknown indication
POTASSIUM CHLORIDE	Concomitant	NOT SPECIFIED					
SYNTHROID	Concomitant	TABLET (ENTERIC-COATED)					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.27.1	
Blood pressure increased	v.27.1	
Chills	v.27.1	
Cyanosis	v.27.1	
Dyspnoea	v.27.1	
Heart rate increased	v.27.1	
Respiratory rate 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
000656484	0	2015-06-11	2015-06-11	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
79 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)
OCTAGAM 10% FOR I.V. INFUSION	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	60 Gram	Total		Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.27.1	
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
000659299	0	2015-07-15	2015-07-15	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
28 Years	Female			Recovering/resolving

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)
CYKLOKAPRON	Concomitant	NOT SPECIFIED					
OCTAGAM 10% FOR I.V. INFUSION	Concomitant	NOT SPECIFIED					
TRANEXAMIC ACID	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	60 Gram	1 every 6 Weeks		Immune thrombocytopenia

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	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
000667232	0	2015-10-27	2015-10-27	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
70 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)
OCTAGAM 10% FOR I.V. INFUSION	Suspect	SOLUTION INTRAVENOUS		42 Gram			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest discomfort	v.27.1	
Dyspnoea	v.27.1	
Heart rate increased	v.27.1	
Tachycardia	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
000668792	0	2015-11-16	2015-11-16	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
80 Years	Male	161 Centimeter	74 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)
OCTAGAM 10% FOR I.V. INFUSION	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	70 Gram	Total	2 Days	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	

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
000668828	0	2015-11-16	2015-11-16	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
68 Years	Female	150 Centimeter	66.2 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)
OCTAGAM 10% FOR I.V. INFUSION	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	25 Gram	1 every 4 Weeks	4 Weeks	Immunodeficiency

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.27.1	
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
000669757	0	2015-11-27	2015-11-27	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
48 Years	Male	192.2 Centimeter	104.5 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER Number
Duplicate	000669077

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
OCTAGAM 10% FOR I.V. INFUSION	Suspect		Intravenous (not otherwise specified)				Chronic spontaneous urticaria
OCTAGAM 10% FOR I.V. INFUSION	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	85 Gram	1 every 1 Days	2 Days	Chronic spontaneous urticaria

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood lactate dehydrogenase increased	v.27.1	
Haemoglobin decreased	v.27.1	
Haemolysis	v.27.1	
Reticulocyte count 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
000669941	0	2015-12-01	2015-12-01	Hospital		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
8 Months	Male	78 Centimeter	10 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER Number
Duplicate	000670917

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
GAMUNEX SINGLE USE VIALS	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	20 Gram			Kawasaki's disease
OCTAGAM 10% FOR I.V. INFUSION	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	20 Gram			Kawasaki's disease

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anti A antibody positive	v.27.1	
Blood bilirubin unconjugated increased	v.27.1	
Blood lactate dehydrogenase abnormal	v.27.1	
Coombs direct test positive	v.27.1	
Haemoglobin decreased	v.27.1	
Haemolysis	v.27.1	
Haptoglobin normal	v.27.1	

Polychromasia	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
000670420	0	2015-12-09	2015-12-09	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	152.3 Centimeter	76.7 Kilogram	Unknown

Link / Duplicate Report Information

Record Type	Link AER Number
Duplicate	000677778

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACTONEL	Concomitant	NOT SPECIFIED					
FOLIC ACID	Concomitant	NOT SPECIFIED					
HYDROCHLOROQUINE	Concomitant	NOT SPECIFIED					
IMURAN	Concomitant	NOT SPECIFIED					
METHOTREXATE	Concomitant	NOT SPECIFIED					
OCTAGAM 10% FOR I.V. INFUSION	Concomitant	Tablets					
OCTAGAM 10% FOR I.V. INFUSION	Concomitant	NOT SPECIFIED					
PAXIL	Concomitant	Tablets					
PREDNISONE	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	70 Gram	1 every 1 Months	1 Days	Dermatomyositis
RANITIDINE	Concomitant	NOT SPECIFIED					
SEPTRA INJECTION	Concomitant	SOLUTION INTRAVENOUS					

VITAMIN D	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)			1 Days	Dermatomyositis

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	
Coombs positive haemolytic anaemia	v.27.1	
Delayed serologic transfusion reaction	v.27.1	
Haemoglobin decreased	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
000670453	0	2015-12-09	2015-12-09	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
8 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)
OCTAGAM 10% FOR I.V. INFUSION	Suspect	SOLUTION INTRAVENOUS		100 ml			Transfusion
OCTAGAM 10% FOR I.V. INFUSION	Suspect	SOLUTION INTRAVENOUS		100 ml			Transfusion

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.27.1	
Culture negative	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
000670945	0	2015-12-18	2015-12-18	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
42 Years		156 Centimeter	74 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER Number
Duplicate	000682321

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
OCTAGAM 10% FOR I.V. INFUSION	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	25 Gram	1 every 3 Months	183 Days	Secondary immunodeficiency

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.27.1	
Oxygen saturation decreased	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
000670959	0	2015-12-18	2015-12-18	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
	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)
OCTAGAM 10% FOR I.V. INFUSION	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	200 ml			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood pressure decreased	v.27.1	
Body temperature decreased	v.27.1	
Heart rate decreased	v.27.1	
Hypotension	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
000675385	0	2016-03-09	2016-03-09	Community		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
46 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER Number
Duplicate	000682348

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
OCTAGAM 10% FOR I.V. INFUSION	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	60 Gram			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest discomfort	v.27.1	
Chest pain	v.27.1	
Transfusion-related circulatory overload	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
000675644	0	2016-03-17	2016-03-17	Hospital		Spontaneous	Other health professional

Serious Report
Serious

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

Patient Information

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

Link / Duplicate Report Information

Record Type	Link AER Number
Duplicate	000681720

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
OCTAGAM 10% FOR I.V. INFUSION	Suspect	SOLUTION INTRAVENOUS					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Acute haemolytic transfusion reaction	v.27.1	
Haemoglobin decreased	v.27.1	
Nonspecific 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
000676654	0	2016-04-11	2016-04-11	Hospital		Spontaneous	Physician

Serious Report
Serious

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

Patient Information

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

Link / Duplicate Report Information

Record Type	Link AER Number
Duplicate	000677625

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AMLODIPINE	Concomitant	NOT SPECIFIED					
CALCIUM	Concomitant	Tablets					
FRAGMIN	Concomitant	NOT SPECIFIED					
HYDROMORPHONE	Concomitant	NOT SPECIFIED					
NAPROXEN SODIUM	Concomitant	NOT SPECIFIED					
OCTAGAM 10% FOR I.V. INFUSION	Concomitant	TABLET (ENTERIC-COATED)					
PANTOLOC	Concomitant	NOT SPECIFIED					
PERINDOPRIL	Concomitant	SOLUTION INTRAVENOUS					
PREDNISONE	Concomitant	NOT SPECIFIED					
PRIVIGEN	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	2000 mg/kg		5 Days	Chronic inflammatory demyelinating polyradiculoneuropathy

VITAMIN D	Suspect	SOLUTION INTRAVENOUS		2000 mg/kg		5 Days	Chronic inflammatory demyelinating polyradiculoneuropathy

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Alanine aminotransferase increased	v.27.1	
Aspartate aminotransferase 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
000683670	0	2016-08-09	2016-08-09	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
	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)
BENADRYL	Concomitant	NOT SPECIFIED					
OCTAGAM 10% FOR I.V. INFUSION	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	125 Milligram/Milliliter			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anti A antibody positive	v.27.1	
Coombs direct test positive	v.27.1	
Face oedema	v.27.1	
Haemolysis	v.27.1	
Oedema peripheral	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
000685064	0	2016-09-12	2016-09-12	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
33 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)
OCTAGAM	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	75 ml			Transfusion

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.27.1	
Dyspnoea	v.27.1	
Hypersensitivity	v.27.1	
Nausea	v.27.1	
Rales	v.27.1	
Transfusion reaction	v.27.1	
Vomiting	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
000687202	0	2016-10-25	2016-10-25	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
82 Years	Male	173 Centimeter	74.5 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)
ACYCLOVIR	Concomitant	Tablets					
AMLODIPINE	Concomitant	NOT SPECIFIED					
ANTINEOPLASTIC(S)	Suspect	SOLUTION INTRAVENOUS					
CETIRIZINE	Concomitant	Tablets					
FERROUS FUMARATE	Concomitant	NOT SPECIFIED					
OCTAGAM	Concomitant	Tablets					
OCTAGAM 10% FOR I.V. INFUSION	Concomitant	NOT SPECIFIED					
PANTOLOC	Concomitant	Powder					
PREDNISONE	Concomitant	Tablets					
REACTINE	Concomitant	NOT SPECIFIED					
ROSUVASTATIN	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	75 Milligram			

SYMBICORT	Concomitant	NOT SPECIFIED					
TOLTERODINE	Concomitant	TABLET (ENTERIC-COATED)					
TYLENOL WITH CODEINE NO. 2 - TAB	Concomitant	Tablets					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.27.1	
Headache	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
000688147	0	2016-11-15	2016-11-15	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
62 Years	Female		68 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER Number
Duplicate	000688854

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CELEXA	Concomitant	NOT SPECIFIED					
DIOVAN	Concomitant	Tablets					
DOMPERIDONE	Concomitant	NOT SPECIFIED					
IMODIUM	Concomitant	Tablets					
MULTIVITAMINE(S)	Concomitant	POWDER FOR SOLUTION INTRAVENOUS					
OCTAGAM 10% FOR I.V. INFUSION	Concomitant	Powder					
PANTO IV	Concomitant	NOT SPECIFIED					
PLAVIX	Concomitant	NOT SPECIFIED					
PREDNISONE	Concomitant	NOT SPECIFIED					
SYMBICORT	Concomitant	Tablets					
SYNTHROID	Concomitant	NOT SPECIFIED					
VENTOLIN	Concomitant	NOT SPECIFIED					

VITAMIN D	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	1000 mg/kg	2 every 1 Months		Polymyositis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Body temperature increased	v.27.1	
Chest pain	v.27.1	
Coombs direct test negative	v.27.1	
Dysphagia	v.27.1	
Heart rate increased	v.27.1	
Hypotension	v.27.1	
Infusion related reaction	v.27.1	
Pain in extremity	v.27.1	
Pharyngeal swelling	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
000688217	0	2016-11-16	2016-11-16	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
81 Years	Female	152 Centimeter	53 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER Number
Duplicate	000697498

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
OCTAGAM 10% FOR I.V. INFUSION	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	50 Gram	1 every 1 Days	2 Days	Myasthenia gravis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.27.1	
Hypoaesthesia oral	v.27.1	
Pharyngeal hypoaesthesia	v.27.1	
Pharyngeal oedema	v.27.1	
Pulmonary congestion	v.27.1	
Rash	v.27.1	
Swollen tongue	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
000688335	0	2016-11-17	2016-11-17	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
81 Years	Female	152 Centimeter	53 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER Number
Duplicate	000688217

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
OCTAGAM 10% FOR I.V. INFUSION	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	100 ml			Myasthenia gravis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.27.1	
Angioedema	v.27.1	
Dysphagia	v.27.1	
Hypoaesthesia oral	v.27.1	
Paraesthesia oral	v.27.1	
Speech disorder	v.27.1	
Throat irritation	v.27.1	
Tongue disorder	v.27.1	

Tongue oedema	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
000688440	0	2016-11-22	2016-11-22	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
1 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)
OCTAGAM 10% FOR I.V. INFUSION	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	65 ml			Kawasaki's disease

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Body temperature increased	v.27.1	
Chills	v.27.1	
Febrile nonhaemolytic transfusion reaction	v.27.1	
Hyperhidrosis	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
000688869	0	2016-11-30	2016-11-30	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
85 Years	Female	160 Centimeter	120 Pound	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER Number
Duplicate	000689699

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
OCTAGAM 10% FOR I.V. INFUSION	Concomitant	LIQUID INTRAVENOUS					
PIPERACILLIN AND TAZOBACTAM FOR INJECTION	Concomitant	POWDER FOR SOLUTION INTRAVENOUS					
POTASSIUM CHLORIDE	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)		1 every 1 Days	2 Days	Immune thrombocytopenia

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood pressure increased	v.27.1	
Chills	v.27.1	
Feeling cold	v.27.1	
Headache	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
000688955	0	2016-12-01	2016-12-01	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
3 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)
OCTAGAM 10% FOR I.V. INFUSION	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	47 ml			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Body temperature increased	v.27.1	
Febrile nonhaemolytic transfusion reaction	v.27.1	
Heart rate 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
000688956	0	2016-12-01	2016-12-01	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
2 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)
OCTAGAM 10% FOR I.V. INFUSION	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	37 ml			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
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	
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
000688957	0	2016-12-01	2016-12-01	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
3 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)
OCTAGAM 10% FOR I.V. INFUSION	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	42 ml			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood pressure increased	v.27.1	
Body temperature increased	v.27.1	
Febrile nonhaemolytic transfusion reaction	v.27.1	
Heart rate increased	v.27.1	
Respiratory rate 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
000689352	0	2016-12-08	2016-12-08	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
19 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER Number
Linked	000689355

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
OCTAGAM 10% FOR I.V. INFUSION	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	55 Gram			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Allergic transfusion reaction	v.27.1	
Body temperature increased	v.27.1	
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
000689355	0	2016-12-08	2016-12-08	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
19 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER Number
Linked	000689352

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
OCTAGAM 10% FOR I.V. INFUSION	Suspect	NOT SPECIFIED	Intravenous (not otherwise specified)	394 ml			
OCTAGAM 10% FOR I.V. INFUSION	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	100 ml			
OCTAGAM 10% FOR I.V. INFUSION	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	200 ml			
OCTAGAM 10% FOR I.V. INFUSION	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	50 ml			
POOLED PLATELETS	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	200 ml			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Allergic transfusion reaction	v.27.1	
Anxiety	v.27.1	

Chest discomfort	v.27.1	
Flushing	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
000689680	0	2016-12-15	2016-12-15	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
71 Years	Male	180 Centimeter	100 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)
HYDROXYQUINE	Concomitant	NOT SPECIFIED					
IMURAN	Concomitant	NOT SPECIFIED					
OCTAGAM 10% FOR I.V. INFUSION	Concomitant	NOT SPECIFIED					
OCTAGAM 10% FOR I.V. INFUSION	Concomitant	Tablets					
PREDNISONE	Concomitant	Tablets					
RISEDRONATE SODIUM	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	60 Gram			Dermatomyositis
SULFAMETHOXAZOLE AND TRIMETHOPRIM	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	5 Gram			Dermatomyositis
THYROID (PFIZER)	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
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
000689925	0	2016-12-19	2016-12-19	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
33 Years	Female		165 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)
AERIUS	Concomitant	NOT SPECIFIED					
CALCIUM	Concomitant	NOT SPECIFIED					
CELLCEPT	Concomitant	NOT SPECIFIED					
IBUPROFEN	Concomitant	NOT SPECIFIED					
MULTIVITAMINE(S)	Concomitant	NOT SPECIFIED					
OCTAGAM 10% FOR I.V. INFUSION	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	60 Gram	1 every 7 Weeks		
TYLENOL	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest discomfort	v.27.1	
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
000689934	0	2016-12-19	2016-12-19	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	66 Inch	58.5 Kilogram	Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER Number
Duplicate	000689978

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASA	Concomitant	Tablets					
BISOPROLOL	Concomitant	Tablets					
BRICANYL TURBUHALER 0.5 MG/AEM	Concomitant	Tablets					
ELAVIL	Concomitant	CAPSULE					
ENTOCORT CAPSULE 3MG	Concomitant	SUSTAINED-RELEASE					
OCTAGAM 10% FOR I.V. INFUSION	Concomitant	NOT SPECIFIED					
SYNTHROID - TAB 25MCG	Concomitant	Tablets					
THYROID TAB 60MG	Suspect	POWDER	Intravenous (not otherwise specified)	50 Gram	1 every 1 Days	2 Days	
		METERED DOSE					
		SOLUTION INTRAVENOUS					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Rash erythematous	v.27.1	
Rash papular	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
000689978	0	2016-12-20	2016-12-20	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
74 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER Number
Duplicate	000689934

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ANTIHISTAMINIC DRUGS	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	50 Gram	Once		Dermatomyositis
OCTAGAM 10% FOR I.V. INFUSION	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Rash	v.27.1	
Rash erythematous	v.27.1	
Rash papular	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
000689980	0	2016-12-20	2016-12-20	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
50 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER Number
Duplicate	000690397

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
OCTAGAM 10% FOR I.V. INFUSION	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	75 Gram	Once		Multifocal motor neuropathy

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dyspepsia	v.27.1	
Dysphagia	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
000689981	0	2016-12-20	2016-12-20	Community		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
32 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER Number
Duplicate	000690421

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
OCTAGAM 10% FOR I.V. INFUSION	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	60 Gram	Once		Dermatomyositis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest discomfort	v.27.1	
Dyspnoea	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
000689982	0	2016-12-20	2016-12-20	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
61 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)
OCTAGAM 10% FOR I.V. INFUSION	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	40 Gram	Once		Guillain-Barre syndrome

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 Information ***AER = Adverse Reaction Report

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000689984	0	2016-12-20	2016-12-20	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
40 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER Number
Duplicate	000690386

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
OCTAGAM 10% FOR I.V. INFUSION	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	35 Gram	Once		Myositis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.27.1	
Chills	v.27.1	
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
000689985	0	2016-12-20	2016-12-20	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
51 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER Number
Duplicate	000690394

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
OCTAGAM 10% FOR I.V. INFUSION	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	50 Gram	Once		Myasthenia gravis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Heart rate increased	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
000690130	0	2016-12-22	2016-12-22	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
26 Years	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER Number
Duplicate	000690493

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
OCTAGAM 10% FOR I.V. INFUSION	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	80 Gram	1 every 1 Days		Immune thrombocytopenia

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
000690377	0	2017-01-03	2017-01-03	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
	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)
OCTAGAM 10% FOR I.V. INFUSION	Suspect	SOLUTION INTRAVENOUS		500 ml			

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
000690636	0	2017-01-06	2017-01-06	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
63 Years	Male	177 Centimeter	100 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER Number
Duplicate	000691349

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
OCTAGAM 10% FOR I.V. INFUSION	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	100 Gram	1 every 4 Weeks	6 Months	Chronic inflammatory demyelinating polyradiculoneuropathy

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
000690812	0	2017-01-11	2017-01-11	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
31 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)
OCTAGAM 10% FOR I.V. INFUSION	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	100 ml	Once		
OCTAGAM 10% FOR I.V. INFUSION	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	200 ml	Once		
OCTAGAM 10% FOR I.V. INFUSION	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	200 ml	Once		
OCTAGAM 10% FOR I.V. INFUSION	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	200 ml	Once		
OCTAGAM 10% FOR I.V. INFUSION	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	100 ml	Once		
OCTAGAM 10% FOR I.V. INFUSION	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	200 ml	Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration

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
000691066	0	2017-01-16	2017-01-16	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
87 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)
AMLODIPINE	Concomitant	NOT SPECIFIED					
ANTIINFECTIVES FOR SYSTEMIC USE	Concomitant	NOT SPECIFIED					
BISOPROLOL	Concomitant	NOT SPECIFIED					
CALCIUM	Concomitant	Tablets					
CYCLOSPORINE	Concomitant	Tablets					
ELIQUIS FILM-COATED	Concomitant	NOT SPECIFIED					
FOLIC ACID	Concomitant	NOT SPECIFIED					
OCTAGAM 10% FOR I.V. INFUSION	Concomitant	Tablets					
PREDNISONE	Concomitant	NOT SPECIFIED					
SYNTHROID TAB 200MCG	Concomitant	NOT SPECIFIED					
VITAMIN B12	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)		1 every 4 Weeks		Necrotising myositis

VITAMIN D	Concomitant	Tablets					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Rash pruritic	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
000691373	0	2017-01-23	2017-01-23	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	65 Inch	74 Kilogram	Recovering/resolving

Link / Duplicate Report Information

Record Type	Link AER Number
Duplicate	000691991

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
OCTAGAM 5% FOR I.V. INFUSION	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	60 Gram	2 every 4 Weeks	1 Days	Dermatomyositis
OCTAGAM 5% FOR I.V. INFUSION	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	10 Gram	2 every 4 Weeks	1 Days	Dermatomyositis
TYLENOL	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Lip swelling	v.27.1	
Pruritus	v.27.1	
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
000691447	0	2017-01-24	2017-01-24	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
	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)
OCTAGAM 10% FOR I.V. INFUSION	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	100 ml			Bone marrow transplant
OCTAGAM 10% FOR I.V. INFUSION	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	50 ml			Bone marrow transplant

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Body temperature increased	v.27.1	
Fatigue	v.27.1	
Headache	v.27.1	
Nausea	v.27.1	
Neutropenia	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
000693043	1	2017-02-23	2017-02-28	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
77 Years	Female	162 Centimeter	57 Kilogram	Recovering/resolving

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					
ACYCLOVIR	Concomitant	NOT SPECIFIED					
ELIQUIS FILM-COATED	Concomitant	Tablets					
GAMUNEX	Concomitant	NOT SPECIFIED					
LEVOTHYROXINE	Concomitant	NOT SPECIFIED					
OCTAGAM 10% FOR I.V. INFUSION	Concomitant	NOT SPECIFIED					
ONDANSETRON	Concomitant	NOT SPECIFIED					
PHENYTOIN	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	40 Gram	1 every 1 Days	1 Days	Encephalitis
PHENYTOIN SODIUM INJECTION USP	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	40 Gram	1 every 1 Days	4 Days	Meningitis aseptic
SENNOSIDES	Concomitant	LIQUID INTRAMUSCULAR					
SOLU-MEDROL	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Haemolysis	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
000693203	0	2017-02-24	2017-02-24	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
57 Years	Male	177.8 Centimeter	102 Kilogram	Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER Number
Duplicate	000703056

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
OCTAGAM 10% FOR I.V. INFUSION	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)		As required		Myasthenia gravis

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
000693482	0	2017-03-03	2017-03-03	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
67 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)
OCTAGAM 10% FOR I.V. INFUSION	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	200 ml			Ventricular assist device insertion
OCTAGAM 10% FOR I.V. INFUSION	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	100 ml			Ventricular assist device insertion
OCTAGAM 10% FOR I.V. INFUSION	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	200 ml			Ventricular assist device insertion
OCTAGAM 10% FOR I.V. INFUSION	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	200 ml			Ventricular assist device insertion

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypersensitivity	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
000696492	0	2017-05-04	2017-05-04	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
	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)
OCTAGAM 5%	Concomitant	NOT SPECIFIED					
OCTAGAM 5%	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	50 ml			Brain injury
OCTAGAM 5%	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	50 ml			Brain injury
TYLENOL	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	27.3 ml			Brain injury

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood pressure increased	v.27.1	
Heart rate decreased	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
000696953	0	2017-05-12	2017-05-12	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
45 Years	Female	173.4 Centimeter	64 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)
OCTAGAM 10% FOR I.V. INFUSION	Suspect	SOLUTION INTRAVENOUS					Dermatomyositis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pruritus	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
000981928	0	2021-12-29	2021-12-29	Hospital		Spontaneous	Nurse

Serious Report
Serious

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
25 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)
OCTAGAM	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	40 Gram	Once	155 Minutes	Antiinflammatory therapy

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypotension	v.27.1	
Hypothermia	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
000993106	0	2022-03-21	2022-03-21	Community		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
74 Years	Female	145 Centimeter	72 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)
OCTAGAM	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	29 Gram	Once		Stem cell transplant

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.27.1	
Hypoxia	v.27.1	
Nausea	v.27.1	
Respiratory distress	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
000995011	0	2022-04-01	2022-04-01	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
4 Years	Male	111 Centimeter	30 Kilogram	Recovering/resolving

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)
OCTAGAM 10% FOR I.V. INFUSION	Suspect	SOLUTION INTRAVENOUS	Intravenous drip	60 Gram	Once		Kawasaki's disease

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Delayed haemolytic transfusion reaction	v.27.1	
Red blood cell spherocytes	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
000997782	0	2022-04-21	2022-04-21	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
38 Years	Female	64 Inch	63 Kilogram	Recovering/resolving

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)
OCTAGAM	Suspect	SOLUTION INTRAVENOUS		60 Gram	Once	3 Hours	Immune thrombocytopenia

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.27.1	
Hypotension	v.27.1	
Musculoskeletal stiffness	v.27.1	
Nausea	v.27.1	
Photophobia	v.27.1	
Pleocytosis	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
001000052	0	2022-05-04	2022-05-04	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
63 Years	Male	178 Centimeter	69 Kilogram	Recovering/resolving

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)
CIPROFLOXACIN	Concomitant	NOT SPECIFIED					
OCTAGAM	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	65 Gram	Once		Immune thrombocytopenia

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.27.1	2 Days
Blood pressure immeasurable	v.27.1	
Body temperature increased	v.27.1	
Heart rate increased	v.27.1	
Oxygen saturation decreased	v.27.1	
Oxygen therapy	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
001001108	0	2022-05-10	2022-05-10	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
62 Years	Male	188 Centimeter	92 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)
OCTAGAM 10% ALSO KNOW AS IMMUNE GLOBULIN (HUMAN). FOR I.V. INFUSION	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	30 Gram	Once		COVID-19 pneumonia

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	
Hyperhidrosis	v.27.1	
Hypertension	v.27.1	
Oxygen saturation decreased	v.27.1	
Pyrexia	v.27.1	

Resuscitation	v.27.1	
Tachycardia	v.27.1	
Tachypnoea	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
001004009	0	2022-05-30	2022-05-30	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
	Male			Recovering/resolving

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)
OCTAGAM	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cough	v.27.1	
Dyspnoea	v.27.1	
Oxygen saturation decreased	v.27.1	
Oxygen therapy	v.27.1	
Tremor	v.27.1	
Vital functions abnormal	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
001009643	0	2022-07-11	2022-07-11	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
	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)
OCTAGAM	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	100 ml			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood pressure decreased	v.27.1	
Erythema	v.27.1	
Hypoaesthesia	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
001016629	0	2022-09-07	2022-09-07	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
76 Years	Male	173 Centimeter	67 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)
OCTAGAM	Suspect	SOLUTION INTRAVENOUS		35 Gram	1 every 1 Months		B-cell lymphoma

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Back pain	v.27.1	
Chills	v.27.1	
Dyspnoea	v.27.1	
Hypertension	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
001017437	0	2022-09-16	2022-09-16	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
30 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)
OCTAGAM 10% FOR I.V. INFUSION	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	20 Gram			
OCTAGAM 10% FOR I.V. INFUSION	Suspect	SOLUTION INTRAVENOUS	Intravenous drip	20 Gram		123 Minutes	
OCTAGAM 10% FOR I.V. INFUSION	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	20 Gram			
OCTAGAM 10% FOR I.V. INFUSION	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	10 Gram			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest discomfort	v.27.1	
Dyspnoea	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
001017465	0	2022-09-16	2022-09-16	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
	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)
BENADRYL	Concomitant	NOT SPECIFIED					
OCTAGAM 10% ALSO KNOW AS IMMUNE GLOBULIN (HUMAN). FOR I.V. INFUSION	Concomitant	NOT SPECIFIED					
TYLENOL	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	7.8 ml			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood pressure decreased	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
001023256	0	2022-11-02	2022-11-02	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
65 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)
OCTAGAM 10% FOR I.V. INFUSION	Suspect	SOLUTION INTRAVENOUS	Intravenous drip	200 Gram	1 every 6 Weeks		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.27.1	
Chills	v.27.1	
Dizziness	v.27.1	
Dyspnoea	v.27.1	
Hypertension	v.27.1	
Hypotension	v.27.1	
Myalgia	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
001027289	0	2022-12-02	2022-12-02	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
	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)
OCTAGAM	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	189 ml		27 Minutes	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.27.1	
Febrile nonhaemolytic transfusion reaction	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
001028112	0	2022-12-07	2022-12-07	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
34 Years	Female	170 Centimeter	113 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)
OCTAGAM	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	50 Gram	Once		Immune system disorder

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.27.1	
Dyspnoea	v.27.1	
Headache	v.27.1	
Nausea	v.27.1	
Tachycardia	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
001032884	0	2023-01-18	2023-01-18	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
76 Years	Male	170 Centimeter	70 Kilogram	Not recovered/not 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)
ARIPIPRAZOLE	Concomitant	Tablets					
BISOPROLOL	Concomitant	NOT SPECIFIED					
CABLIVI	Concomitant	NOT SPECIFIED					
CEFTRIAXONE FOR INJECTION USP	Concomitant	NOT SPECIFIED					
FINASTERIDE	Concomitant	NOT SPECIFIED					
HALOPERIDOL	Concomitant	KIT					
LASIX	Concomitant	POWDER FOR SOLUTION INTRAMUSCULAR					
MIRTAZAPINE	Concomitant	Tablets	Unknown				
MYCOPHENOLATE MOFETIL	Concomitant	Tablets					
OCTAGAM	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	65 Gram		1 Days	Immune thrombocytopenia

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Haemolytic 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
001033830	0	2023-01-25	2023-01-25	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
29 Years	Female	173 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)
NAPROXEN	Concomitant	NOT SPECIFIED					
OCTAGAM	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	30 Gram	Once		Primary immunodeficiency syndrome

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.27.1	
Headache	v.27.1	
Infusion site erythema	v.27.1	
Infusion site pruritus	v.27.1	
Malaise	v.27.1	
Musculoskeletal stiffness	v.27.1	
Nausea	v.27.1	

Photophobia	v.27.1	
Pyrexia	v.27.1	
Vision blurred	v.27.1	
Vomiting	v.27.1	8 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
001038009	0	2023-02-24	2023-02-24	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
48 Years	Female	164 Centimeter	94 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)
AZATHIOPRINE	Concomitant	NOT SPECIFIED					
OCTAGAM 10% ALSO KNOW AS IMMUNE GLOBULIN (HUMAN). FOR I.V. INFUSION	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	5 Gram	1 every 1 Days		Myasthenia gravis
OCTAGAM 10% ALSO KNOW AS IMMUNE GLOBULIN (HUMAN). FOR I.V. INFUSION	Suspect	SOLUTION INTRAVENOUS		30 Gram	1 every 1 Days		Myasthenia gravis
PYRIDOSTIGMINE BROMIDE	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.27.1	1 Days
Pharyngeal swelling	v.27.1	

Respiratory distress	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
001039491	0	2023-03-08	2023-03-08	Community		Spontaneous	Consumer/other non health professional

Serious Report
Serious

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
76 Years	Male			Not recovered/not 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)
APIXABAN	Concomitant	Tablets					
OCTAGAM 10% FOR I.V. INFUSION	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)		Once	6 Hours	Neuropathy peripheral
OCTAGAM 10% FOR I.V. INFUSION	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)		Once	8 Hours	Neuropathy peripheral

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dermatitis allergic	v.27.1	
Discomfort	v.27.1	
Gait disturbance	v.27.1	
Headache	v.27.1	
Hypoaesthesia	v.27.1	

Impaired quality of life	v.27.1	
Neuropathy peripheral	v.27.1	
Paraesthesia	v.27.1	
Peripheral swelling	v.27.1	
Rash	v.27.1	
Skin ulcer	v.27.1	
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
001039498	0	2023-03-08	2023-03-08	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
17 Years	Female	170 Centimeter	59 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)
OCTAGAM 10% FOR I.V. INFUSION	Concomitant	Capsules					
PREDNISONE	Concomitant	NOT SPECIFIED					
RITUXIMAB	Concomitant	NOT SPECIFIED					
TACROLIMUS	Concomitant						
VALGANCICLOVIR	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	90 Gram	Once	1 Days	Anti-HLA antibody test positive

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.27.1	
Musculoskeletal stiffness	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
001039527	0	2023-03-08	2023-03-08	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
60 Years	Male	179 Centimeter	138 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	Concomitant	NOT SPECIFIED					
OCTAGAM 10% FOR I.V. INFUSION	Concomitant	NOT SPECIFIED					
PREDNISONE	Concomitant						
RITUXIMAB	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	37 Gram	1 every 1 Days	323 Days	Guillain-Barre syndrome

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chills	v.27.1	
Heart rate increased	v.27.1	
Hypertension	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
001039534	0	2023-03-08	2023-03-08	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
32 Years	Female	151 Centimeter	31 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)
ATROVENT	Concomitant	NOT SPECIFIED	Unknown				
AZITHROMYCIN	Concomitant	NOT SPECIFIED	Unknown				
CEFTRIAXONE FOR INJECTION USP	Concomitant	NOT SPECIFIED					
OCTAGAM 10% FOR I.V. INFUSION	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	15 Gram	1 every 4 Weeks		Hypogammaglobulinaemia
OCTAGAM 10% FOR I.V. INFUSION	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	15 Gram	1 every 4 Weeks		Hypogammaglobulinaemia
SALBUTAMOL	Concomitant	LIQUID INTRAVENOUS					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.27.1	5 Days
Dyspnoea	v.27.1	

Hypersensitivity	v.27.1	
Hypoxia	v.27.1	
Tachycardia	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
001042722	0	2023-03-31	2023-03-31	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
	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)
BENADRYL	Concomitant	NOT SPECIFIED					
MONTELUKAST	Suspect	SOLUTION INTRAVENOUS	Intravenous drip	19 Gram			Composite lymphoma
OCTAGAM ALSO KNOW AS IMMUNE GLOBULIN (HUMAN). FOR I.V. INFUSION	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Back pain	v.27.1	
Blood pressure diastolic decreased	v.27.1	
Chills	v.27.1	
Febrile nonhaemolytic transfusion reaction	v.27.1	
Heart rate increased	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
001047983	0	2023-05-12	2023-05-12	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
34 Years	Female	159 Centimeter	57 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)
OCTAGAM	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	55 Gram	1 every 1 Days		Myelopathy

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Back pain	v.27.1	
Chills	v.27.1	
Hypotension	v.27.1	
Hypoxia	v.27.1	
Muscle spasms	v.27.1	
Oxygen therapy	v.27.1	
Pyrexia	v.27.1	
Respiratory rate increased	v.27.1	

Tachycardia	v.27.1	
Tachypnoea	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
001050979	0	2023-06-05	2023-06-05	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
60 Years	Female		65 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)
HYDROCORTISONE	Concomitant	NOT SPECIFIED					
OCTAGAM	Concomitant	Tablets					
OCTAGAM	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	5 Gram	Once		Immunoglobulins decreased
PEPCID	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	9 Gram	Once		Immunoglobulins decreased

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Body temperature increased	v.27.1	
Chills	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
001059997	0	2023-08-18	2023-08-18	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
49 Years	Male	177 Centimeter	93 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)
OCTAGAM	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	60 Gram	Once	1 Days	Immune thrombocytopenia
OCTAGAM	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	20 Gram	Once		Immune thrombocytopenia

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.27.1	
Musculoskeletal stiffness	v.27.1	
Nausea	v.27.1	2 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
001076518	0	2023-12-21	2023-12-21	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
77 Years	Female	160 Centimeter	61 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)
OCTAGAM 10% FOR I.V. INFUSION	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	30 Gram			Hypogammaglobulinaemia

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.27.1	
Anaphylactoid reaction	v.27.1	
Dyspnoea	v.27.1	
Oxygen saturation decreased	v.27.1	
Positive airway pressure therapy	v.27.1	
Transfusion-associated dyspnoea	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
001078685	0	2024-01-18	2024-01-18	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
32 Years	Female	170 Centimeter	59 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)
OCTAGAM	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	35 Gram	1 every 4 Weeks	3 Hours	Immunodeficiency common variable

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.27.1	
Back pain	v.27.1	
Headache	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
E2B_01795982	1	2018-03-21	2018-06-18	Clinical Study	PHHY2016CA181726	Study	

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
65 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)
APO-RANITIDINE	Concomitant	NOT SPECIFIED	Unknown	2 Dosage forms	1 every 1 Days		Product used for unknown indication
DIOVAN	Suspect		Unknown	1 Dosage forms	1 every 1 Days		Product used for unknown indication
JANUVIA	Concomitant	NOT SPECIFIED	Unknown	1 Dosage forms	1 every 1 Days		Blood cholesterol
LIPITOR	Concomitant	NOT SPECIFIED	Unknown	1 Dosage forms	1 every 1 Days		Product used for unknown indication
METFORMIN	Concomitant	SOLUTION INTRAVENOUS	Unknown				Autoimmune disorder
MONTELUKAST SODIUM	Suspect	POWDER FOR SOLUTION SUBCUTANEOUS	Subcutaneous	300 Milligram			Chronic spontaneous urticaria
OCTAGAM	Concomitant	Tablets	Unknown	1 Dosage forms	1 every 1 Days		Product used for unknown indication
PREDNISONE	Suspect	NOT SPECIFIED	Oral	80 Milligram	1 every 1 Days		Hypertension
REACTINE	Concomitant	NOT SPECIFIED	Unknown	1 Dosage forms	1 every 1 Days		Product used for unknown indication
XOLAIR	Suspect		Unknown	4 Dosage forms	1 every 1 Days		Diabetes mellitus

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
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
E2B_01795991	1	2018-03-21	2018-06-18	Clinical Study	PHHY2016CA181726	Study	

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
65 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)
APO-RANITIDINE	Suspect	POWDER FOR SOLUTION SUBCUTANEOUS	Subcutaneous	300 Milligram			Chronic spontaneous urticaria
DIOVAN	Concomitant	NOT SPECIFIED	Unknown	1 Dosage forms	1 every 1 Days		Product used for unknown indication
JANUVIA	Concomitant	Tablets	Unknown	1 Dosage forms	1 every 1 Days		Product used for unknown indication
LIPITOR	Concomitant	NOT SPECIFIED	Unknown	1 Dosage forms	1 every 1 Days		Blood cholesterol
METFORMIN	Suspect	NOT SPECIFIED	Oral	80 Milligram	1 every 1 Days		Hypertension
MONTELUKAST SODIUM	Concomitant	SOLUTION INTRAVENOUS	Unknown				Autoimmune disorder
OCTAGAM	Suspect		Unknown	4 Dosage forms	1 every 1 Days		Diabetes mellitus
PREDNISONE	Suspect		Unknown	1 Dosage forms	1 every 1 Days		Product used for unknown indication
REACTINE	Concomitant	NOT SPECIFIED	Unknown	2 Dosage forms	1 every 1 Days		Product used for unknown indication
XOLAIR	Concomitant	NOT SPECIFIED	Unknown	1 Dosage forms	1 every 1 Days		Product used for unknown indication

Adverse Reaction Term Information

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