Health Canada Santé Canada

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2024-12-06 - 01:51:56 AM
Initial Received Date:	1965-01-01 to 2024-07-31
Latest Received Date:	N/A
Total Number of Reports:	30 Report(s)

Brand Name/Active Ingredient: 'OCTAGAM'
Search Date Criteria: 1965-01-01 to 2024-07-31
Reaction Term(s): All/Tous
Serious report?: Both
Type of Report: All
Source of Report: All
Gender: All
Report Outcome: All
Age: All

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

Canada

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Report Information

***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000685064	0	2016-09-12	2016-09-12	Hospital		Spontaneous	Other health professional

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

Patient Information

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

Link / Duplicate Report Information

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

Product Information

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

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

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Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000687202	0	2016-10-25	2016-10-25	Hospital		Spontaneous	Other health professional

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
82 Years	Male	173 Centimeter	74 Kilogram	Recovered/resolved

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACYCLOVIR	Concomitant	NOT SPECIFIED					
AMLODIPINE	Concomitant	Tablets					
ANTINEOPLASTIC(S)	Concomitant	NOT SPECIFIED					
CETIRIZINE	Concomitant	Tablets					
FERROUS FUMARATE	Concomitant	NOT SPECIFIED					
OCTAGAM	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	75.0 Milligram			
OCTAGAM 10% FOR I.V. INFUSION	Suspect	SOLUTION INTRAVENOUS					
PANTOLOC	Concomitant	TABLET (ENTERIC-COATED)					
PREDNISONE	Concomitant	NOT SPECIFIED					
REACTINE	Concomitant	NOT SPECIFIED					

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ROSUVASTATIN	Concomitant	Tablets					
SYMBICORT	Concomitant	Powder					
TOLTERODINE	Concomitant	Tablets					
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	

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Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000689699	0	2016-12-13	2016-12-13	MAH	GAM-417-16-CA	Spontaneous	Other health professional

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

Patient Information

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

Link / Duplicate Report Information

Record Type	Link AER** Number
Duplicate	000688869

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
DEXTROSE	Concomitant	NOT SPECIFIED					
OCTAGAM	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	20.0 Gram	1 every 2 Days		Immune thrombocytopenia
PIPERACILLIN/TAZOBACTAM	Concomitant	NOT SPECIFIED					
POTASSIUM CHLORIDE	Concomitant	NOT SPECIFIED					

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	

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

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Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000691734	0	2017-01-26	2017-01-26	MAH	GAM-016-17-CA	Spontaneous	Other health professional

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

Patient Information

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

Link / Duplicate Report Information

Record Type	Link AER** Number
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)	90.0 Gram	1 every 4 Weeks		Necrotising myositis

Adverse Reaction Term Information

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

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Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000697498	1	2017-05-24	2017-06-23	MAH	GAM-119-17-CA	Spontaneous	Other health professional

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
81 Years	Female			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	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	100.0 Gram	1 every 16 Weeks		Myasthenia gravis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.27.1	
Hypoaesthesia	v.27.1	
Hypoaesthesia oral	v.27.1	
Pharyngeal hypoaesthesia	v.27.1	
Pharyngeal oedema	v.27.1	
Pharyngeal oedema	v.27.1	
Pulmonary congestion	v.27.1	

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

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000697501	1	2017-05-24	2017-06-23	MAH	GAM-118-17-CA	Spontaneous	Other health professional

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

Patient Information

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

Link / Duplicate Report Information

Record Type	Link AER** Number
Duplicate	000688335

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
DIPHENHYDRAMINE	Concomitant	NOT SPECIFIED					
HYDROCORTISONE	Concomitant	NOT SPECIFIED					
OCTAGAM	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	20.0 Gram			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	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Speech disorder	v.27.1	
Throat irritation	v.27.1	
Tongue disorder	v.27.1	
Tongue oedema	v.27.1	
Vomiting	v.27.1	

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000981928	0	2021-12-29	2021-12-29	Hospital		Spontaneous	Nurse

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

Patient Information

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

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
OCTAGAM	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	40.0 Gram	Once	155.0 Minutes	Haemophagocytic lymphohistiocytosis, Antiinflammatory therapy

Adverse Reaction Term Information

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

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000993106	0	2022-03-21	2022-03-21	Community		Spontaneous	Other health professional

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
74 Years	Female	145 Centimeter	72 Kilogram	Recovered/resolved

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
OCTAGAM	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	29.0 Gram	Once		Stem cell transplant, Secondary immunodeficiency, Hypogammaglobulinaemia

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	

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000997115	1	2022-04-14	2022-04-22	MAH		Spontaneous	Other health professional

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
4 Years	Male	111 Centimeter	30 Kilogram	Recovered/resolved

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
OCTAGAM	Suspect	SOLUTION INTRAVENOUS	Intravenous drip	60.0 Gram			Kawasaki's disease

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anti A antibody positive	v.27.1	
Haemolytic transfusion reaction	v.27.1	
Red blood cell spherocytes present	v.27.1	

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Report Information ***AER = Adverse Reaction Report*

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000997782	0	2022-04-21	2022-04-21	Hospital		Spontaneous	Other health professional

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
38 Years	Female	64 Inch	63 Kilogram	Recovering/resolving

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
OCTAGAM	Suspect	SOLUTION INTRAVENOUS		60.0 Gram	Once	3.0 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	

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

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Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
001000052	0	2022-05-04	2022-05-04	Hospital		Spontaneous	Other health professional

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
63 Years	Male	178 Centimeter	69 Kilogram	Recovering/resolving

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
CIPROFLOXACIN	Concomitant	NOT SPECIFIED					
OCTAGAM	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	65.0 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	

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Report Information ***AER = Adverse Reaction Report*

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001004009	0	2022-05-30	2022-05-30	Hospital		Spontaneous	Other health professional

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male			Recovering/resolving

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
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	

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Report Information ***AER = Adverse Reaction Report*

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001009643	0	2022-07-11	2022-07-11	Hospital		Spontaneous	Other health professional

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male			Recovered/resolved

Link / Duplicate Report Information

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

Product Information

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

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Report Information ***AER = Adverse Reaction Report*

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001016629	0	2022-09-07	2022-09-07	Hospital		Spontaneous	Other health professional

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
76 Years	Male	173 Centimeter	67 Kilogram	Recovered/resolved

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
OCTAGAM	Suspect	SOLUTION INTRAVENOUS		35.0 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	

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Report Information ***AER = Adverse Reaction Report*

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001027289	0	2022-12-02	2022-12-02	Hospital		Spontaneous	Other health professional

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male			Recovered/resolved

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
OCTAGAM	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	189.0 ml		27.0 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	

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Report Information ***AER = Adverse Reaction Report*

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001028112	0	2022-12-07	2022-12-07	Hospital		Spontaneous	Other health professional

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
34 Years	Female	170 Centimeter	113 Kilogram	Recovered/resolved

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
OCTAGAM	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	50.0 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	

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Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
001032884	0	2023-01-18	2023-01-18	Hospital		Spontaneous	Physician

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
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.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ARIPIPRAZOLE	Concomitant	NOT SPECIFIED					
BISOPROLOL	Concomitant	Tablets	Unknown				
CABLIVI	Concomitant	KIT					
CEFTRIAXONE FOR INJECTION USP	Concomitant	POWDER FOR SOLUTION INTRAMUSCULAR					
FINASTERIDE	Concomitant	Tablets					
HALOPERIDOL	Concomitant	NOT SPECIFIED					
LASIX	Concomitant	NOT SPECIFIED					
MIRTAZAPINE	Concomitant	Tablets					
MYCOPHENOLATE MOFETIL	Concomitant	NOT SPECIFIED					
OCTAGAM	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	65.0 Gram		1.0 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 Runtime: 2024-12-06 - 01:51:56 AM
Initial Received Date: 1965-01-01 to 2024-07-31
Latest Received Date: N/A
Total Number of Reports: 30 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report 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?	Death:		Disability:		Congenital Anomaly:	
Serious	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.	

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)	30.0 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	8 Days
Malaise	v.27.1	
Musculoskeletal stiffness	v.27.1	
Nausea	v.27.1	

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

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-06 - 01:51:56 AM
Initial Received Date: 1965-01-01 to 2024-07-31
Latest Received Date: N/A
Total Number of Reports: 30 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
001035439	1	2023-02-06	2023-10-02	MAH		Spontaneous	Physician

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
29 Years	Female	173 Centimeter	50 Kilogram	Recovered/resolved

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
NAPROXEN	Concomitant	NOT SPECIFIED					
OCTAGAM	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	30.0 Gram	Total		Primary immunodeficiency syndrome

Adverse Reaction Term Information

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

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Nausea	v.27.1	
Photophobia	v.27.1	
Pyrexia	v.27.1	
Vision blurred	v.27.1	
Vomiting	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-06 - 01:51:56 AM
Initial Received Date: 1965-01-01 to 2024-07-31
Latest Received Date: N/A
Total Number of Reports: 30 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
001038121	0	2023-02-26	2023-02-26	MAH		Spontaneous	Consumer/other non health professional

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

Patient Information

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

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
OCTAGAM	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	29.0 Gram	Once		Hypogammaglobulinaemia

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 Runtime: 2024-12-06 - 01:51:56 AM
Initial Received Date: 1965-01-01 to 2024-07-31
Latest Received Date: N/A
Total Number of Reports: 30 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report 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?	Death:		Disability:		Congenital Anomaly:	
Serious	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.	

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)	55.0 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	

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

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-06 - 01:51:56 AM
Initial Received Date: 1965-01-01 to 2024-07-31
Latest Received Date: N/A
Total Number of Reports: 30 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
001048962	1	2023-05-23	2023-10-31	MAH		Spontaneous	Other health professional

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
34 Years	Female	159 Centimeter	57 Kilogram	Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
OCTAGAM	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	55.0 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	
Chills	v.27.1	
Hypotension	v.27.1	
Hypoxia	v.27.1	
Muscle spasms	v.27.1	
Oxygen therapy	v.27.1	

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

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-06 - 01:51:56 AM
Initial Received Date: 1965-01-01 to 2024-07-31
Latest Received Date: N/A
Total Number of Reports: 30 Report(s)

Report Information ***AER = Adverse Reaction Report*

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
60 Years	Female		65 Kilogram	Recovered/resolved

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
HYDROCORTISONE	Concomitant	NOT SPECIFIED					
OCTAGAM	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	5.0 Gram	Once		Immunoglobulins decreased
OCTAGAM	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	9.0 Gram	Once		Immunoglobulins decreased
PEPCID	Concomitant	Tablets					

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 Runtime: 2024-12-06 - 01:51:56 AM
Initial Received Date: 1965-01-01 to 2024-07-31
Latest Received Date: N/A
Total Number of Reports: 30 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
001053718	1	2023-06-22	2023-07-27	MAH		Spontaneous	Consumer/other non health professional

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

Patient Information

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

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
OCTAGAM	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	35.0 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	
Chills	v.27.1	
Dyspnoea	v.27.1	
Hypertension	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-06 - 01:51:56 AM
Initial Received Date: 1965-01-01 to 2024-07-31
Latest Received Date: N/A
Total Number of Reports: 30 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
001053956	0	2023-06-26	2023-06-26	MAH		Spontaneous	Consumer/other non health professional

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male			Recovering/resolving

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
OCTAGAM	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)				Product used for unknown indication

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 Runtime: 2024-12-06 - 01:51:56 AM
Initial Received Date: 1965-01-01 to 2024-07-31
Latest Received Date: N/A
Total Number of Reports: 30 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report 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?	Death:		Disability:		Congenital Anomaly:	
Serious	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.	

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)	60.0 Gram	Once	1.0 Days	Immune thrombocytopenia
OCTAGAM	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	20.0 Gram	Once		Immune thrombocytopenia

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.27.1	2 Days
Musculoskeletal stiffness	v.27.1	
Nausea	v.27.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-06 - 01:51:56 AM
Initial Received Date: 1965-01-01 to 2024-07-31
Latest Received Date: N/A
Total Number of Reports: 30 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
001061770	0	2023-08-31	2023-08-31	MAH		Spontaneous	Consumer/other non health professional

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

Patient Information

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

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
OCTAGAM	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	80.0 Gram	Total	1.0 Days	Immune thrombocytopenia

Adverse Reaction Term Information

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

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2024-12-06 - 01:51:56 AM
Initial Received Date: 1965-01-01 to 2024-07-31
Latest Received Date: N/A
Total Number of Reports: 30 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
001066667	1	2023-10-02	2023-10-30	MAH		Spontaneous	Consumer/other non health professional

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

Patient Information

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

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
APIXABAN	Concomitant	Tablets					
OCTAGAM	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)			28.0 Days	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	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
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 Runtime: 2024-12-06 - 01:51:56 AM
Initial Received Date: 1965-01-01 to 2024-07-31
Latest Received Date: N/A
Total Number of Reports: 30 Report(s)

Report Information ***AER = Adverse Reaction Report*

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
32 Years	Female	170 Centimeter	59 Kilogram	Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
OCTAGAM	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	35.0 Gram	1 every 4 Weeks	3.0 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 Runtime: 2024-12-06 - 01:51:56 AM
Initial Received Date: 1965-01-01 to 2024-07-31
Latest Received Date: N/A
Total Number of Reports: 30 Report(s)

Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_05905528	2	2022-09-09	2023-01-24	MAH	2022TUS061423	Spontaneous	Other health professional

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
27 Years	Male	168 Centimeter	55 Kilogram	Recovered/resolved

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
DEXPANTHENOL/ERGOCALCIFEROL/FOLIC ACID/NICOTINAMIDE/RIBOFLAVIN/THIAMINE HYDROCHLORIDE/VITAMIN A/VITAMIN C	Concomitant						
FLOVENT	Concomitant	NOT SPECIFIED		2.0 Dosage forms	2 every 1 Days		
GAMMAGARD LIQUID ALSO KNOW AS IMMUNE GLOBULIN (HUMAN)	Suspect	Solution for infusion	Intravenous (not otherwise specified)	30.0 Gram	1 every 1 Days		Immunodeficiency
GAMMAGARD LIQUID ALSO KNOW AS IMMUNE GLOBULIN (HUMAN)	Suspect	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)	30.0 Gram	1 every 1 Days	1440.0 Minutes	Immunodeficiency

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
GAMMAGARD LIQUID ALSO KNOW AS IMMUNE GLOBULIN (HUMAN)	Suspect	Solution for infusion	Intravenous (not otherwise specified)	30.0 Gram	1 every 1 Days	1.0 Days	Immunodeficiency
GAMMAGARD LIQUID ALSO KNOW AS IMMUNE GLOBULIN (HUMAN)	Suspect	Solution for infusion	Intravenous (not otherwise specified)	150.0 ml			Immunodeficiency
GAMMAGARD LIQUID ALSO KNOW AS IMMUNE GLOBULIN (HUMAN)	Suspect	Solution for infusion	Intravenous (not otherwise specified)	115.0 ml	1 every 1 Days	1440.0 Minutes	Immunodeficiency
OCTAGAM	Suspect	SOLUTION INTRAVENOUS	Unknown	20.0 Gram			Product used for unknown indication
VENTOLIN	Concomitant			2.0 Dosage forms			
VENTOLIN	Concomitant	NOT SPECIFIED		2.0 Dosage forms	2 every 1 Days		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Back pain	v.27.1	1 Days
Body temperature increased	v.27.1	
Chills	v.27.1	
Febrile nonhaemolytic transfusion reaction	v.27.1	
Hypertension	v.27.1	
Hypoxia	v.27.1	
Oxygen saturation decreased	v.27.1	
Oxygen therapy	v.27.1	
Tachycardia	v.27.1	