Health Canada Santé Canada

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2019-03-07 - 01:58:06 PM
Initial Received Date:	1970-01-01 to 2018-11-30
Latest Received Date:	N/A
Total Number of Reports:	237 Report(s)

Brand Name/Active Ingredient: measles
Search Date Criteria: 1970-01-01 to 2018-11-30
Reaction Term(s): All/Tous
Serious report?: Yes
Type of Report: All
Source of Report: All
Gender: All
Report Outcome: All
Age: 0 - 7

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
000000584	0	1973-08-02	1973-08-02	Hospital		Spontaneous	

Serious report?	Death:		Disability:		Congenital Anomaly:	
Yes	Life Threatening:		Hospitalization:	Yes	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.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ATTENUVAX	Suspect	NOT SPECIFIED	Parenteral	0.5 mL			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pyrexia	v.21.1	
Seizure	v.21.1	

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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
000000585	0	1973-08-02	1973-08-02	Hospital		Spontaneous	

Serious report?	Death:		Disability:		Congenital Anomaly:	
Yes	Life Threatening:		Hospitalization:	Yes	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.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ATTENUVAX	Suspect	NOT SPECIFIED	Parenteral	0.5 mL			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pyrexia	v.21.1	
Seizure	v.21.1	

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***AER = Adverse Reaction Report*

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000002147	0	1974-02-15	1974-02-15	Community		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
11 Months	Male			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ATTENUVAX	Suspect	NOT SPECIFIED	Parenteral				
QUAD VACCINE	Suspect	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.21.1	
Muscle twitching	v.21.1	
Pyrexia	v.21.1	
Seizure	v.21.1	

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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
000002399	0	1974-03-14	1974-03-14	MAH		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
12 Months	Female			Death

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)
ATTENUVAX	Suspect	NOT SPECIFIED	Parenteral				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Encephalitis	v.21.1	
Pyrexia	v.21.1	
Respiratory arrest	v.21.1	
Seizure	v.21.1	

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Report Information

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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
000002637	0	1974-03-28	1974-03-28	Community		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
21 Months	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)
ATTENUVAX	Suspect	NOT SPECIFIED	Parenteral			6.0 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Ataxia	v.21.1	
Balance disorder	v.21.1	
Encephalitis	v.21.1	
Pyrexia	v.21.1	
Rash maculo-papular	v.21.1	

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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
000002876	0	1974-04-26	1974-04-26	Community		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
39 Months	Female			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ATTENUVAX	Suspect	NOT SPECIFIED	Parenteral				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Delirium	v.21.1	
Photophobia	v.21.1	
Pyrexia	v.21.1	
Rash	v.21.1	

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000006133	0	1975-03-24	1975-03-24	Hospital		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
17 Months			9 Kilograms	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)
M-R-VAX	Suspect	LIQUID SUBCUTANEOUS	Subcutaneous		1 every 1 Day(s)		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pyrexia	v.21.1	

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000007752	0	1975-10-07	1975-10-07	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
14 Months		76 Centimetres	13 Kilograms	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)
MMR	Suspect	LIQUID SUBCUTANEOUS	Subcutaneous	0.5 mL	1 every 1 Day(s)	1.0 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Febrile convulsion	v.21.1	
Pyrexia	v.21.1	

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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
000009341	0	1976-03-17	1976-03-17			Spontaneous	Physician

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
13 Months			11 Kilograms	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)
MMR	Suspect	LIQUID SUBCUTANEOUS	Subcutaneous	0.5 mL	1 every 1 Day(s)	1.0 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Febrile convulsion	v.21.1	
Pyrexia	v.21.1	
Rash erythematous	v.21.1	

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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
000009860	0	1976-04-23	1976-04-23			Spontaneous	Physician

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
15 Months	Female			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MMR	Suspect	LIQUID SUBCUTANEOUS	Subcutaneous	1.0 Dosage forms	1 every 1 Day(s)	1.0 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pyrexia	v.21.1	
Rash erythematous	v.21.1	
Seizure	v.21.1	

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000009867	0	1976-04-28	1976-04-28			Spontaneous	Physician

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
3 Years	Female			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
RUBELLA VACCINE	Suspect	NOT SPECIFIED	Subcutaneous	1.0 Dosage forms	1 every 1 Day(s)	1.0 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Angioedema	v.21.1	

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000010089	0	1976-05-10	1976-05-10	MAH		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
13 Months	Male			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ATTENUVAX	Suspect	NOT SPECIFIED	Parenteral				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Febrile convulsion	v.21.1	
Pyrexia	v.21.1	

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000010963	0	1976-09-09	1976-09-09			Spontaneous	Physician

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
13 Months	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)
MMR	Suspect	LIQUID SUBCUTANEOUS	Subcutaneous		1 every 1 Day(s)		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Decreased appetite	v.21.1	
Encephalitis	v.21.1	
Pyrexia	v.21.1	
Rash maculo-papular	v.21.1	
Vomiting	v.21.1	

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000012147	0	1977-01-26	1977-01-26			Spontaneous	Consumer Or Other Non Health Professional

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
15 Months	Male			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ATTENUVAX	Suspect	NOT SPECIFIED	Parenteral	0.5 mL	1 every 1 Day(s)		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Febrile convulsion	v.21.1	
Pyrexia	v.21.1	

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000012148	0	1977-01-26	1977-01-26	MAH		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
14 Months	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)
MMR	Suspect	LIQUID SUBCUTANEOUS		0.5 mL			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Encephalitis	v.21.1	
Hemiplegia	v.21.1	
Respiratory failure	v.21.1	
Seizure	v.21.1	

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000014062	0	1977-07-12	1977-07-12	Other		Spontaneous	

Serious report?	Death:		Disability:		Congenital Anomaly:	
Yes	Life Threatening:		Hospitalization:	Yes	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.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ATTENUVAX	Suspect	NOT SPECIFIED	Parenteral				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Encephalitis	v.21.1	
Febrile convulsion	v.21.1	
Pyrexia	v.21.1	

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000014066	0	1977-07-12	1977-07-12	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
13 Months	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)
ATTENUVAX	Suspect	NOT SPECIFIED	Subcutaneous				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bronchitis	v.21.1	
Conjunctivitis	v.21.1	
Erythema	v.21.1	
Pyrexia	v.21.1	
Rhinitis	v.21.1	

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000014403	0	1977-04-29	1977-04-29			Spontaneous	Consumer Or Other Non Health Professional

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
2 Years	Female			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
LIRUGEN	Suspect	POWDER FOR SOLUTION SUBCUTANEOUS			1 every 1 Day(s)	1.0 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Paralysis	v.21.1	
Pyrexia	v.21.1	
Rash	v.21.1	
Seizure	v.21.1	

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000015132	0	1977-10-31	1977-10-31			Spontaneous	Physician

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
1 Years	Female	79 Centimetres	12 Kilograms	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)
MMR	Suspect	LIQUID SUBCUTANEOUS	Subcutaneous	1.0 Dosage forms	1 every 1 Day(s)		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Lethargy	v.21.1	
Leukopenia	v.21.1	
Pyrexia	v.21.1	
Rash maculo-papular	v.21.1	
Vomiting	v.21.1	

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000016806	0	1978-04-26	1978-04-26	MAH		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
16 Months	Female	72 Centimetres	11 Kilograms	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)
MMR	Suspect	LIQUID SUBCUTANEOUS					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Encephalopathy	v.21.1	
Pyrexia	v.21.1	
Rash	v.21.1	
Vomiting	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000018276	0	1978-08-17	1978-08-17			Spontaneous	Physician

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
15 Months	Male	81 Centimetres	11 Kilograms	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)
DIPHTHERIA AND TETANUS TOXOIDS WITH PERTUSSIS VACCINE ADSORBED	Concomitant	LIQUID INTRAMUSCULAR	Subcutaneous				
MMR	Suspect	LIQUID SUBCUTANEOUS		1.0 Dosage forms	1 every 1 Day(s)	1.0 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Febrile convulsion	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000018766	0	1978-10-11	1978-10-11	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
18 Months				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)
ATTENUVAX	Suspect	NOT SPECIFIED	Parenteral				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pyrexia	v.21.1	
Rash	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000019989	0	1979-02-19	1979-02-19	Hospital		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
18 Months	Male			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MEASLES VACCINE	Suspect	POWDER FOR SOLUTION SUBCUTANEOUS					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dehydration	v.21.1	
Pharyngitis	v.21.1	
Pyrexia	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000019993	0	1979-02-19	1979-02-19	Hospital		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
1 Years	Female			Unknown

Link / Duplicate Report Information

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

Product Information

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

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pyrexia	v.21.1	
Rash erythematous	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000019994	0	1979-02-19	1979-02-19	Hospital		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
1 Years	Female			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
RUBELLA VACCINE	Suspect	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Febrile convulsion	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000021505	0	1979-05-16	1979-05-16	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
1 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)
ATTENUVAX	Suspect	NOT SPECIFIED	Parenteral				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Febrile convulsion	v.21.1	
Rash erythematous	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000021947	0	1979-09-18	1979-09-18	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
14 Months	Male		10 Kilograms	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)
MMR	Suspect	LIQUID SUBCUTANEOUS	Subcutaneous			1.0 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Febrile convulsion	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000021950	0	1979-09-18	1979-09-18	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
17 Months	Female		12 Kilograms	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)
MMR	Suspect	LIQUID SUBCUTANEOUS	Subcutaneous				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pyrexia	v.21.1	
Rash erythematous	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000023521	0	1980-02-28	1980-02-28	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
7 Years	Male			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ATTENUVAX	Suspect	NOT SPECIFIED	Subcutaneous	0.5 mL			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Oedema	v.21.1	
Urticaria	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000024450	0	1980-04-09	1980-04-09	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
1 Years	Female			Unknown

Link / Duplicate Report Information

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

Product Information

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

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Febrile convulsion	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000024601	0	1980-06-11	1980-06-11	Other		Spontaneous	

Serious report?	Death:		Disability:		Congenital Anomaly:	
Yes	Life Threatening:		Hospitalization:	Yes	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.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MMR	Suspect	LIQUID SUBCUTANEOUS	Subcutaneous				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bronchospasm	v.21.1	
Pyrexia	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000024602	0	1980-06-05	1980-06-05	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
9 Months	Male		7 Kilograms	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)
ATTENUVAX	Suspect	NOT SPECIFIED	Subcutaneous	1.0 mL			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pyrexia	v.21.1	
Rash	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000024673	0	1980-02-18	1980-02-18	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
13 Months	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)
MEASLES VACCINE	Suspect	POWDER FOR SOLUTION SUBCUTANEOUS					
TEGRETOL	Drug used to treat AE	NOT SPECIFIED	Oral	100.0 Milligram	3 every 1 Day(s)		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Electroencephalogram abnormal	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000026308	0	1980-11-21	1980-11-21	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
15 Months	Female			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MERUVAX	Suspect	POWDER FOR SOLUTION SUBCUTANEOUS					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Thrombocytopenia	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000026733	0	1981-01-22	1981-01-22	Other		Spontaneous	

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

Patient Information

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

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MMR	Suspect	LIQUID SUBCUTANEOUS	Subcutaneous	0.5 mL			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Encephalitis	v.21.1	
Melaena	v.21.1	
Paralysis	v.21.1	
Vomiting	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000028070	0	1981-05-04	1981-05-04	Hospital		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
13 Months	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)
MMR	Suspect	LIQUID SUBCUTANEOUS	Subcutaneous	0.5 mL	1 every 1 Day(s)	1.0 Day(s)	
TEMPRA	Drug used to treat AE	NOT SPECIFIED	Oral				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Febrile convulsion	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000028312	0	1981-05-25	1981-05-25	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
23 Months	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)
ATTENUVAX	Suspect	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Febrile convulsion	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000029035	0	1981-08-26	1981-08-26	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
18 Months	Female			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MMR	Suspect	LIQUID SUBCUTANEOUS	Subcutaneous	0.5 mL			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cough	v.21.1	
Febrile convulsion	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000029036	0	1981-08-26	1981-08-26	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
15 Months	Male			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MMR	Suspect	LIQUID SUBCUTANEOUS	Subcutaneous	0.5 mL			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pyrexia	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000029083	0	1981-08-24	1981-08-24	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
14 Months	Female			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MMR II	Suspect	LIQUID SUBCUTANEOUS					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Febrile convulsion	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000029911	0	1981-10-16	1981-10-16	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
2 Years	Female			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ATTENUVAX	Suspect	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Febrile convulsion	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000030242	0	1981-06-01	1981-06-01	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
2 Years	Female			Death

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)
MMR II	Suspect	LIQUID SUBCUTANEOUS				1.0 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Coma	v.21.1	
Vomiting	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000030302	0	1981-11-17	1981-11-17	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
18 Months	Male			Unknown

Link / Duplicate Report Information

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

Product Information

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

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Coma	v.21.1	
Decreased appetite	v.21.1	
Fatigue	v.21.1	
Muscular weakness	v.21.1	
Sleep disorder	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000030571	0	1981-12-08	1981-12-08	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
18 Months	Male	84 Centimetres	11 Kilograms	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)
MMR II	Suspect	LIQUID SUBCUTANEOUS	Subcutaneous	0.5 mL			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pyrexia	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000030603	0	1981-12-24	1981-12-24	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
1 Years	Female			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MMR	Suspect	LIQUID SUBCUTANEOUS	Subcutaneous				
TYLENOL	Drug used to treat AE	NOT SPECIFIED	Oral				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Febrile convulsion	v.21.1	
Pyrexia	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000030863	0	1982-01-19	1982-01-19	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
1 Years	Male			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MEASLES VACCINE	Suspect	POWDER FOR SOLUTION SUBCUTANEOUS					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cyanosis	v.21.1	
Pallor	v.21.1	
Somnolence	v.21.1	
Stupor	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000030864	0	1982-01-19	1982-01-19	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
22 Months	Female			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ATTENUVAX	Suspect	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Conjunctivitis	v.21.1	
Irritability	v.21.1	
Pharyngitis	v.21.1	
Pyrexia	v.21.1	
Rash	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000030868	0	1982-01-04	1982-01-04	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
14 Months	Female			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASPIRIN	Drug used to treat AE	NOT SPECIFIED	Oral				
MMR II	Suspect	LIQUID SUBCUTANEOUS					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pyrexia	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000030876	0	1982-01-04	1982-01-04	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
1 Years	Female			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MMR II	Suspect	LIQUID SUBCUTANEOUS					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Petechiae	v.21.1	
Purpura	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000030877	0	1982-01-12	1982-01-12	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
4 Years	Male			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MMR II	Suspect	LIQUID SUBCUTANEOUS					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain	v.21.1	
Eye pain	v.21.1	
Fatigue	v.21.1	
Irritability	v.21.1	
Lymphadenopathy	v.21.1	
Pharyngitis	v.21.1	
Pyrexia	v.21.1	
Rhinitis	v.21.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Vomiting	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000030878	0	1982-01-12	1982-01-12	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
1 Years				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)
MMR II	Suspect	LIQUID SUBCUTANEOUS					
TYLENOL	Drug used to treat AE	NOT SPECIFIED	Oral				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Diarrhoea	v.21.1	
Irritability	v.21.1	
Pyrexia	v.21.1	
Rash	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000030879	0	1982-01-12	1982-01-12	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
2 Years	Male			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETYLSALICYLIC ACID	Drug used to treat AE	TABLET		1.0 Dosage forms			
MMR	Suspect	LIQUID SUBCUTANEOUS					
PHENERGAN SYRUP 10MG/5ML	Drug used to treat AE	SYRUP		5.0 Milligram			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Diarrhoea	v.21.1	
Dyspnoea	v.21.1	
Irritability	v.21.1	
Pyrexia	v.21.1	
Vomiting	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000030881	0	1982-01-12	1982-01-12	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
18 Months	Male			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MMR II	Suspect	LIQUID SUBCUTANEOUS					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pyrexia	v.21.1	
Rash	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000031062	0	1982-02-08	1982-02-08	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
1 Years	Female			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ASPIRIN	Drug used to treat AE	NOT SPECIFIED	Oral		6 every 1 Day(s)		
ATTENUVAX	Suspect	NOT SPECIFIED	Subcutaneous				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pyrexia	v.21.1	
Seizure	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000032052	0	1982-04-05	1982-04-05	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
15 Months	Female			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MMR II	Suspect	LIQUID SUBCUTANEOUS			1 every 1 Day(s)	1.0 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Lymphadenopathy	v.21.1	
Pyrexia	v.21.1	
Rash	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000032424	0	1982-05-19	1982-05-19	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
1 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)
MMR	Suspect	LIQUID SUBCUTANEOUS	Subcutaneous				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Face oedema	v.21.1	
Pyrexia	v.21.1	
Rash	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000032432	0	1982-05-14	1982-05-14	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
15 Months	Male	81 Centimetres	12 Kilograms	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)
ASPIRIN	Drug used to treat AE	NOT SPECIFIED	Oral				
MMR II	Suspect	LIQUID SUBCUTANEOUS		0.5 mL			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Irritability	v.21.1	
Pyrexia	v.21.1	
Rash	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000032824	0	1982-06-28	1982-06-28	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
20 Months	Female			Unknown

Link / Duplicate Report Information

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

Product Information

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

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dehydration	v.21.1	
Diabetes mellitus	v.21.1	
Pyrexia	v.21.1	
Respiratory disorder	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000033608	0	1982-07-21	1982-07-21	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
19 Months	Female			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MMR II	Suspect	LIQUID SUBCUTANEOUS					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Febrile convulsion	v.21.1	
Pyrexia	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000035146	0	1982-11-15	1982-11-15	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
20 Months	Female			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ATTENUVAX	Suspect	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pyrexia	v.21.1	
Seizure	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000036047	0	1983-03-24	1983-03-24	Other		Spontaneous	Physician

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
16 Months	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)
MMR II	Suspect	LIQUID SUBCUTANEOUS					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Haemolytic anaemia	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000036267	0	1983-01-24	1983-01-24	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
1 Years	Male			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MMR II	Suspect	LIQUID SUBCUTANEOUS					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pyrexia	v.21.1	
Seizure	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000037800	0	1983-02-24	1983-02-24	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
4 Years	Male			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MMR II	Suspect	LIQUID SUBCUTANEOUS					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000038036	0	1983-03-28	1983-03-28	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
1 Years	Male			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MMR II	Suspect	LIQUID SUBCUTANEOUS					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pruritus	v.21.1	
Pyrexia	v.21.1	
Rash	v.21.1	
Seizure	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000038047	0	1983-03-16	1983-03-16	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
18 Months	Female			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MMR II	Suspect	LIQUID SUBCUTANEOUS					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Encephalitis	v.21.1	
Meningitis	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000039479	0	1983-07-20	1983-07-20	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
15 Months	Female			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MMR II	Suspect	LIQUID SUBCUTANEOUS					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Facial paralysis	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000040376	0	1983-10-27	1983-10-27	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
18 Months	Male			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MMR II	Suspect	LIQUID SUBCUTANEOUS					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Conjunctivitis	v.21.1	
Erythema	v.21.1	
Photophobia	v.21.1	
Pyrexia	v.21.1	
Rash	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000041543	0	1983-12-06	1983-12-06	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
18 Months	Female			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MMR II	Suspect	LIQUID SUBCUTANEOUS					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pyrexia	v.21.1	
Seizure	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000042381	0	1984-01-23	1984-01-23	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
15 Months	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)
MMR II	Suspect	LIQUID SUBCUTANEOUS					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pyrexia	v.21.1	
Seizure	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000043305	0	1984-04-17	1984-04-17	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
13 Months	Male	80 Centimetres	13 Kilograms	Recovered/resolved

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETYLSALICYLIC ACID	Drug used to treat AE	NOT SPECIFIED					
AMPICILLIN	Drug used to treat AE	NOT SPECIFIED		125.0 Milligram			
MMR II	Suspect	LIQUID SUBCUTANEOUS		0.5 mL		1.0 Day(s)	
TYLENOL	Drug used to treat AE	NOT SPECIFIED	Oral	5.0 mL			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pyrexia	v.21.1	
Seizure	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000043908	0	1984-06-22	1984-06-22	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
1 Years	Male			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
I.V. SOLUTIONS	Drug used to treat AE	NOT SPECIFIED					
MMR II	Suspect	LIQUID SUBCUTANEOUS					
TEMPRA	Drug used to treat AE	NOT SPECIFIED	Oral				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.21.1	
Asthenia	v.21.1	
Pyrexia	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000044636	0	1984-11-12	1984-11-12	Hospital		Spontaneous	

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

Patient Information

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

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MMR II	Suspect	LIQUID SUBCUTANEOUS					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Neutropenia	v.21.1	
Pyrexia	v.21.1	
Rash	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000045013	0	1984-07-18	1984-07-18	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
4 Years	Female			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETYLSALICYLIC ACID	Drug used to treat AE	NOT SPECIFIED					
ILOSONE	Drug used to treat AE	NOT SPECIFIED	Oral				
MMR II	Suspect	LIQUID SUBCUTANEOUS				1.0 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cellulitis	v.21.1	
Injection site reaction	v.21.1	
Pain	v.21.1	
Pyrexia	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000047788	0	1985-05-03	1985-05-03	Hospital		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
13 Months	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)
AMOXIL	Drug used to treat AE	NOT SPECIFIED					
BACTRIM ROCHE SUSPENSION PAEDIATRIC	Concomitant	SUSPENSION ORAL	Oral			1.0 Day(s)	
MMR II	Suspect	LIQUID SUBCUTANEOUS					
TYLENOL	Drug used to treat AE	NOT SPECIFIED	Oral				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Decreased appetite	v.21.1	
Pyrexia	v.21.1	
Rash	v.21.1	
Vomiting	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000048312	0	1985-07-03	1985-07-03	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
1 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)
MMR II	Suspect	LIQUID SUBCUTANEOUS					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pharyngitis	v.21.1	
Rash	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000048403	0	1985-07-25	1985-07-25	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
15 Months	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)
MMR II	Suspect	LIQUID SUBCUTANEOUS					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Decreased appetite	v.21.1	
Pyrexia	v.21.1	
Rash	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000048724	0	1985-07-05	1985-07-05	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
15 Months	Male			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MMR II	Suspect	LIQUID SUBCUTANEOUS		1.0 Dosage forms	1 every 1 Day(s)	1.0 Day(s)	
TYLENOL	Drug used to treat AE	TABLET	Oral		6 every 1 Day(s)	4.0 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Decreased appetite	v.21.1	
Pyrexia	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000048960	0	1985-09-16	1985-09-16	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
16 Months	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)
MMR II	Suspect	LIQUID SUBCUTANEOUS					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cough	v.21.1	
Otitis media	v.21.1	
Pyrexia	v.21.1	
Rash	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000049222	0	1984-12-12	1984-12-12	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
22 Months	Female			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MMR II	Suspect	LIQUID SUBCUTANEOUS					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pyrexia	v.21.1	
Rash	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000049268	0	1984-12-03	1984-12-03	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
1 Years	Male		10 Kilograms	Recovered/resolved

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETYLSALICYLIC ACID	Drug used to treat AE	NOT SPECIFIED					
MMR II	Suspect	LIQUID SUBCUTANEOUS		0.5 mL			
TYLENOL	Drug used to treat AE	NOT SPECIFIED	Oral				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pyrexia	v.21.1	
Rash	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000050779	0	1985-04-24	1985-04-24	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
1 Years	Female			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETYLSALICYLIC ACID	Drug used to treat AE	NOT SPECIFIED					
AMOXIL	Drug used to treat AE	NOT SPECIFIED					
MMR II	Suspect	LIQUID SUBCUTANEOUS	Subcutaneous		1 every 1 Day(s)	1.0 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Crying	v.21.1	
Decreased appetite	v.21.1	
Erythema	v.21.1	
Pain	v.21.1	
Pharyngitis	v.21.1	
Pyrexia	v.21.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Rash	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000051000	0	1985-01-16	1985-01-16	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
16 Months	Female			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MMR II	Suspect	LIQUID SUBCUTANEOUS				1.0 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Seizure	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000051006	0	1985-05-13	1985-05-13	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
17 Months	Male	81 Centimetres	11 Kilograms	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)
MMR II	Suspect	LIQUID SUBCUTANEOUS	Subcutaneous				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Crying	v.21.1	
Rash	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000051029	0	1985-04-03	1985-04-03	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
19 Months	Female	82 Centimetres	14 Kilograms	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)
MMR II	Suspect	LIQUID SUBCUTANEOUS	Subcutaneous	0.5 mL	1 every 1 Day(s)	1.0 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Balance disorder	v.21.1	
Pyrexia	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000051038	0	1985-01-30	1985-01-30	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
1 Years	Male	75 Centimetres	10 Kilograms	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)
ILOSONE	Drug used to treat AE	NOT SPECIFIED	Oral				
MMR II	Suspect	LIQUID SUBCUTANEOUS	Subcutaneous		1 every 1 Day(s)	1.0 Day(s)	
PHENOBARBITAL	Drug used to treat AE	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Febrile convulsion	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000051040	0	1985-05-03	1985-05-03	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
1 Years	Male	78 Centimetres	11 Kilograms	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)
MMR II	Suspect	LIQUID SUBCUTANEOUS			1 every 1 Day(s)	1.0 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pyrexia	v.21.1	
Seizure	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000051043	0	1985-06-24	1985-06-24	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
13 Months	Female	80 Centimetres	11 Kilograms	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)
MMR II	Suspect	LIQUID SUBCUTANEOUS	Subcutaneous		1 every 1 Day(s)	1.0 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pyrexia	v.21.1	
Rash	v.21.1	
Seizure	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000051044	0	1985-07-05	1985-07-05	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
1 Years	Male	78 Centimetres	11 Kilograms	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)
MMR II	Suspect	LIQUID SUBCUTANEOUS		0.5 mL	1 every 1 Day(s)	1.0 Day(s)	
PENBRITIN	Drug used to treat AE	NOT SPECIFIED		1.0 Teaspoonful	4 every 1 Day(s)		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Crying	v.21.1	
Erythema	v.21.1	
Face oedema	v.21.1	
Irritability	v.21.1	
Lethargy	v.21.1	
Pyrexia	v.21.1	
Rash	v.21.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Sleep disorder	v.21.1	
Tonsillitis	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000051045	0	1985-09-23	1985-09-23	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
19 Months	Female	81 Centimetres	13 Kilograms	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)
MMR II	Suspect	LIQUID SUBCUTANEOUS		0.5 mL	1 every 1 Day(s)	1.0 Day(s)	
TYLENOL	Drug used to treat AE	NOT SPECIFIED	Oral				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypersensitivity	v.21.1	
Pyrexia	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000051046	0	1985-10-25	1985-10-25	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
13 Months	Male	74 Centimetres	9 Kilograms	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)
MMR II	Suspect	LIQUID SUBCUTANEOUS			1 every 1 Day(s)	1.0 Day(s)	
OXYGEN	Drug used to treat AE	GAS FOR INHALATION					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dyspnoea	v.21.1	
Oculogyric crisis	v.21.1	
Pyrexia	v.21.1	
Seizure	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000051819	0	1985-06-04	1985-06-04	Other		Spontaneous	

Serious report?	Death:	Disability:	Congenital Anomaly:
Yes	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.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MMR II	Suspect	LIQUID SUBCUTANEOUS			1 every 1 Day(s)	1.0 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactoid reaction	v.21.1	
Apnoea	v.21.1	
Dizziness	v.21.1	
Pain	v.21.1	
Pallor	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000051824	0	1985-05-22	1985-05-22	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
13 Months	Female			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MMR II	Suspect	LIQUID SUBCUTANEOUS			1 every 1 Day(s)	1.0 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cough	v.21.1	
Decreased appetite	v.21.1	
Irritability	v.21.1	
Pyrexia	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000051829	0	1985-05-30	1985-05-30	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
6 Years	Male			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MMR II	Suspect	LIQUID SUBCUTANEOUS			1 every 1 Day(s)	1.0 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Lymphadenopathy	v.21.1	
Pharyngitis	v.21.1	
Pyrexia	v.21.1	
Viral infection	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000051850	0	1985-02-28	1985-02-28	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
2 Years	Male			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ANTIINFECTIVES FOR SYSTEMIC USE	Drug used to treat AE	NOT SPECIFIED					
MMR II	Suspect	LIQUID SUBCUTANEOUS			1 every 1 Day(s)	1.0 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Eye pain	v.21.1	
Headache	v.21.1	
Infection	v.21.1	
Lymphadenopathy	v.21.1	
Malaise	v.21.1	
Musculoskeletal stiffness	v.21.1	
Torticollis	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000051859	0	1985-10-11	1985-10-11	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
1 Years	Female			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MMR II	Suspect	LIQUID SUBCUTANEOUS			1 every 1 Day(s)	1.0 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Diarrhoea	v.21.1	
Infection	v.21.1	
Otitis media	v.21.1	
Pyrexia	v.21.1	
Rash maculo-papular	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000051862	0	1985-08-21	1985-08-21	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
1 Years	Male			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MMR II	Suspect	LIQUID SUBCUTANEOUS			1 every 1 Day(s)	1.0 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Generalised tonic-clonic seizure	v.21.1	
Syncope	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000051865	0	1985-07-15	1985-07-15	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
16 Months	Male			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MMR II	Suspect	LIQUID SUBCUTANEOUS			1 every 1 Day(s)	1.0 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Lymphadenopathy	v.21.1	
Pyrexia	v.21.1	
Rash	v.21.1	
Seizure	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000051866	0	1985-07-29	1985-07-29	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
13 Months	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)
MMR II	Suspect	LIQUID SUBCUTANEOUS			1 every 1 Day(s)	1.0 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthritis	v.21.1	
Crying	v.21.1	
Infection	v.21.1	
Irritability	v.21.1	
Pain	v.21.1	
Pyrexia	v.21.1	
Synovitis	v.21.1	
Torticollis	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000051867	0	1985-07-29	1985-07-29	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
14 Months	Male			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ANTIINFECTIVES FOR SYSTEMIC USE	Drug used to treat AE	NOT SPECIFIED					
MMR II	Suspect	LIQUID SUBCUTANEOUS			1 every 1 Day(s)	1.0 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Decreased appetite	v.21.1	
Infection	v.21.1	
Irritability	v.21.1	
Lymphadenopathy	v.21.1	
Periorbital oedema	v.21.1	
Pyrexia	v.21.1	
Rash maculo-papular	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000051871	0	1985-07-30	1985-07-30	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
18 Months	Female			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MMR II	Suspect	LIQUID SUBCUTANEOUS			1 every 1 Day(s)	1.0 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Decreased appetite	v.21.1	
Pyrexia	v.21.1	
Rash	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000053305	0	1986-03-20	1986-03-20	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
16 Months	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)
MMR II	Suspect	LIQUID SUBCUTANEOUS	Subcutaneous	0.5 mL	1 every 1 Day(s)	1.0 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Croup infectious	v.21.1	
Pyrexia	v.21.1	
Rash erythematous	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000055017	0	1986-03-25	1986-03-25	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
12 Months	Female			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MMR II	Suspect	LIQUID SUBCUTANEOUS					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cough	v.21.1	
Periorbital oedema	v.21.1	
Pyrexia	v.21.1	
Rhinitis	v.21.1	
Viral infection	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000055218	0	1986-02-18	1986-02-18	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
7 Months	Female			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MMR II	Suspect	LIQUID SUBCUTANEOUS					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.21.1	
Pyrexia	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

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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
000055353	0	1986-06-18	1986-06-18	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
20 Months	Male	77 Centimetres	9 Kilograms	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)
MMR II	Suspect	LIQUID SUBCUTANEOUS	Subcutaneous	0.5 mL			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Gastroenteritis	v.21.1	
Pyrexia	v.21.1	
Rash	v.21.1	
Seizure	v.21.1	

Canada Vigilance
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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
000055359	0	1986-03-12	1986-03-12	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
14 Months	Male	71 Centimetres	13 Kilograms	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)
AMOXIL	Drug used to treat AE	NOT SPECIFIED					
MMR II	Suspect	LIQUID SUBCUTANEOUS	Subcutaneous	0.5 mL			
PHENOBARBITAL	Drug used to treat AE	NOT SPECIFIED		25.0 Milligram	2 every 1 Day(s)		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pyrexia	v.21.1	
Seizure	v.21.1	

Canada Vigilance
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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
000055375	0	1986-02-10	1986-02-10	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
1 Years	Male			Recovered/resolved with sequelae

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)
MMR II	Suspect	LIQUID SUBCUTANEOUS					
PHENOBARBITAL	Drug used to treat AE	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pyrexia	v.21.1	
Seizure	v.21.1	

Canada Vigilance
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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
000055431	0	1986-04-14	1986-04-14	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
14 Months	Male	76 Centimetres	10 Kilograms	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)
MMR II	Suspect	LIQUID SUBCUTANEOUS	Subcutaneous	0.5 mL			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pyrexia	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

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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
000057286	0	1986-08-14	1986-08-14	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
14 Months	Male			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MMR II	Suspect	LIQUID SUBCUTANEOUS					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Conjunctivitis	v.21.1	
Decreased appetite	v.21.1	
Eye pain	v.21.1	
Lymphadenopathy	v.21.1	
Pyrexia	v.21.1	

Canada Vigilance
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Latest Received Date: N/A
Total Number of Reports: 237 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
000057594	0	1986-11-04	1986-11-04	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
16 Months	Female			Death

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)
MMR II	Suspect	LIQUID SUBCUTANEOUS					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Death	v.21.1	
Encephalopathy	v.21.1	
Seizure	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

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Latest Received Date: N/A
Total Number of Reports: 237 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
000057676	0	1986-11-17	1986-11-17	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
12 Months	Male	76 Centimetres	11 Kilograms	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)
MMR II	Suspect	LIQUID SUBCUTANEOUS	Subcutaneous	0.5 mL			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.21.1	
Somnolence	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

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Latest Received Date: N/A
Total Number of Reports: 237 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
000057694	0	1986-12-18	1986-12-18	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
1 Years	Male			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETAMINOPHEN	Drug used to treat AE	NOT SPECIFIED	Oral		6 every 1 Day(s)		
MMR II	Suspect	LIQUID SUBCUTANEOUS	Subcutaneous				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Diarrhoea	v.21.1	
Flushing	v.21.1	
Pyrexia	v.21.1	
Rash	v.21.1	
Vomiting	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

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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
000057699	0	1986-12-16	1986-12-16	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
19 Months	Male	85 Centimetres	10 Kilograms	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)
TEMPRA	Drug used to treat AE	NOT SPECIFIED	Oral		6 every 1 Day(s)		
TRIVIRIX	Suspect	LIQUID SUBCUTANEOUS	Subcutaneous				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Decreased appetite	v.21.1	
Erythema	v.21.1	
Headache	v.21.1	
Irritability	v.21.1	
Lymphadenopathy	v.21.1	
Pyrexia	v.21.1	
Weight decreased	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

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Latest Received Date: N/A
Total Number of Reports: 237 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
000058168	0	1987-02-18	1987-02-18	Hospital		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
13 Months	Male	76 Centimetres	10 Kilograms	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)
ADRENALIN CHLORIDE SOL 1:1000	Drug used to treat AE	SOLUTION NASAL	Subcutaneous	0.1 mL			
TRIVIRIX	Suspect	LIQUID SUBCUTANEOUS	Subcutaneous				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactoid reaction	v.21.1	
Cyanosis	v.21.1	
Dyspnoea	v.21.1	
Eye disorder	v.21.1	
Face oedema	v.21.1	
Flushing	v.21.1	
Hyperhidrosis	v.21.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Mydriasis	v.21.1	
Pallor	v.21.1	

Canada Vigilance
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Latest Received Date: N/A
Total Number of Reports: 237 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
000058235	0	1987-02-09	1987-02-09	Hospital		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
1 Years	Male			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
TRIVIRIX	Suspect	LIQUID SUBCUTANEOUS	Subcutaneous	0.5 mL	1 every 1 Day(s)		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactoid reaction	v.21.1	
Cyanosis	v.21.1	
Dyspnoea	v.21.1	

Canada Vigilance
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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
000059341	0	1987-01-30	1987-01-30	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
1 Years	Female			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
TEMPRA	Drug used to treat AE	NOT SPECIFIED	Oral		1 every 1 Day(s)	1.0 Day(s)	
TRIVIRIX	Suspect	LIQUID SUBCUTANEOUS	Subcutaneous				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dysphonia	v.21.1	
Pyrexia	v.21.1	
Rash	v.21.1	
Swelling	v.21.1	

Canada Vigilance
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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
000059372	0	1987-03-27	1987-03-27	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
1 Years	Male			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETAMINOPHEN	Drug used to treat AE	NOT SPECIFIED	Oral				
TEMPRA	Drug used to treat AE	NOT SPECIFIED	Oral				
TRIVIRIX	Suspect	LIQUID SUBCUTANEOUS					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Muscle twitching	v.21.1	
Pyrexia	v.21.1	
Seizure	v.21.1	
Syncope	v.21.1	
Visual impairment	v.21.1	

Canada Vigilance
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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
000059612	0	1987-01-05	1987-01-05	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
15 Months	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)
TRIVIRIX	Suspect	LIQUID SUBCUTANEOUS	Subcutaneous	0.5 mL	1 every 1 Day(s)	1.0 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Parotid gland enlargement	v.21.1	
Pyrexia	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

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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
000059614	0	1987-01-05	1987-01-05	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
18 Months	Male			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
TRIVIRIX	Suspect	LIQUID SUBCUTANEOUS		0.5 mL			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Parotitis	v.21.1	
Pyrexia	v.21.1	

Canada Vigilance
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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
000059870	0	1987-01-30	1987-01-30	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
1 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)
MMR II	Suspect	LIQUID SUBCUTANEOUS	Subcutaneous		1 every 1 Day(s)	1.0 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Agitation	v.21.1	
Chills	v.21.1	
Hyperhidrosis	v.21.1	
Muscle spasticity	v.21.1	
Musculoskeletal stiffness	v.21.1	
Pain	v.21.1	
Pallor	v.21.1	
Vomiting	v.21.1	

Canada Vigilance
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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
000059892	0	1987-01-20	1987-01-20	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
1 Years	Female			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ANTIINFECTIVES FOR SYSTEMIC USE	Drug used to treat AE	NOT SPECIFIED					
ASPIRIN	Drug used to treat AE	NOT SPECIFIED	Rectal				
MMR II	Suspect	LIQUID SUBCUTANEOUS	Subcutaneous				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Febrile convulsion	v.21.1	
Irritability	v.21.1	
Otitis media	v.21.1	
Pyrexia	v.21.1	

Canada Vigilance
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Latest Received Date: N/A
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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
000060077	0	1987-02-20	1987-02-20	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
6 Years	Female			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
TRIVIRIX	Suspect	LIQUID SUBCUTANEOUS	Subcutaneous		1 every 1 Day(s)	1.0 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Parotid gland enlargement	v.21.1	

Canada Vigilance
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Latest Received Date: N/A
Total Number of Reports: 237 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
000060141	0	1987-09-14	1987-09-14	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
5 Years	Male		18 Kilograms	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)
TRIVIRIX	Suspect	LIQUID SUBCUTANEOUS	Subcutaneous		1 every 1 Day(s)		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.21.1	
Pain	v.21.1	
Pyrexia	v.21.1	
Torticollis	v.21.1	
Vomiting	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000060146	0	1987-09-21	1987-09-21	Hospital		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
14 Months	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)
TRIVIRIX	Suspect	LIQUID SUBCUTANEOUS					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pyrexia	v.21.1	
Viral infection	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000060147	0	1987-09-21	1987-09-21	Hospital		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
13 Months	Male		12 Kilograms	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)
ANTIINFECTIVES FOR SYSTEMIC USE	Drug used to treat AE	NOT SPECIFIED					
TEMPRA	Drug used to treat AE	NOT SPECIFIED	Oral				
TRIVIRIX	Suspect	LIQUID SUBCUTANEOUS					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pyrexia	v.21.1	
Rash maculo-papular	v.21.1	
Seizure	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000060180	0	1986-12-31	1986-12-31	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
14 Months	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)
MMR II	Suspect	LIQUID SUBCUTANEOUS	Subcutaneous				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Apathy	v.21.1	
Decreased appetite	v.21.1	
Diarrhoea	v.21.1	
Seizure	v.21.1	
Vomiting	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000060350	0	1987-05-25	1987-05-25	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
1 Years	Male			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MEGACILLIN	Drug used to treat AE	NOT SPECIFIED	Oral				
TRIVIRIX	Suspect	LIQUID SUBCUTANEOUS	Subcutaneous				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Infection	v.21.1	
Oedema	v.21.1	
Pain	v.21.1	
Pharyngitis	v.21.1	
Pyrexia	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000060502	0	1987-04-29	1987-04-29	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
18 Months	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)
DIPHTHERIA TOXOID	Concomitant	LIQUID SUBCUTANEOUS	Subcutaneous				
MMR II	Suspect	LIQUID SUBCUTANEOUS			1 every 1 Day(s)		
SABIN	Concomitant	NOT SPECIFIED					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cyanosis	v.21.1	
Irritability	v.21.1	
Pyrexia	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000060508	0	1987-04-21	1987-04-21	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
22 Months	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)
DIPHTHERIA AND TETANUS TOXOIDS WITH PERTUSSIS VACCINE ADSORBED	Suspect	LIQUID INTRAMUSCULAR	Intramuscular	0.5 mL			
MMR II	Suspect	LIQUID SUBCUTANEOUS		1.0 Dosage forms			
SABIN	Suspect	NOT SPECIFIED	Oral	2.0 Drops			
TEMPRA	Concomitant	NOT SPECIFIED	Oral				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Eye disorder	v.21.1	
Irritability	v.21.1	
Lethargy	v.21.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Tremor	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000060510	0	1987-06-05	1987-06-05	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
18 Months	Male			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MMR II	Suspect	LIQUID SUBCUTANEOUS	Subcutaneous				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Seizure	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000060514	0	1987-06-10	1987-06-10	Hospital		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
3 Years	Female			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MMR II	Suspect	LIQUID SUBCUTANEOUS	Subcutaneous				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Decreased appetite	v.21.1	
Irritability	v.21.1	
Lymphadenopathy	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000060797	0	1987-01-29	1987-01-29	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
5 Years	Female			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MMR II	Suspect	LIQUID SUBCUTANEOUS					
SEPTRA	Concomitant	NOT SPECIFIED	Oral				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Eye disorder	v.21.1	
Febrile convulsion	v.21.1	
Pyrexia	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000060799	0	1987-01-16	1987-01-16	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
5 Years	Male			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MMR II	Suspect	LIQUID SUBCUTANEOUS					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Lethargy	v.21.1	
Pain	v.21.1	
Rhinitis	v.21.1	
Salivary gland enlargement	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000061118	0	1987-11-04	1987-11-04	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
12 Months	Female			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ADRENALIN CHLORIDE SOL 1:1000	Drug used to treat AE	SOLUTION NASAL	Subcutaneous	0.1 mL			
TRIVIRIX	Suspect	LIQUID SUBCUTANEOUS	Subcutaneous	0.5 mL			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactoid reaction	v.21.1	
Cyanosis	v.21.1	
Dyspnoea	v.21.1	
Face oedema	v.21.1	
Hyperhidrosis	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000062897	0	1986-12-01	1986-12-01	Other		Spontaneous	Physician

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
9 Months	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)
MMR II	Suspect	LIQUID SUBCUTANEOUS					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Rash maculo-papular	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000067353	0	1988-01-26	1988-01-26	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
14 Months	Female			Unknown

Link / Duplicate Report Information

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

Product Information

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

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Parotitis	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000067355	0	1988-01-26	1988-01-26	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
13 Months	Male			Unknown

Link / Duplicate Report Information

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

Product Information

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

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Parotitis	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000067356	0	1988-01-26	1988-01-26	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
14 Months				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)
TRIVIRIX	Suspect	LIQUID SUBCUTANEOUS					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Parotitis	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000067357	0	1988-01-26	1988-01-26	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
14 Months	Male			Unknown

Link / Duplicate Report Information

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

Product Information

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

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Parotitis	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000067358	0	1988-01-26	1988-01-26	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
20 Months	Male			Unknown

Link / Duplicate Report Information

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

Product Information

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

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Parotitis	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000067359	0	1988-01-26	1988-01-26	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
15 Months	Male			Unknown

Link / Duplicate Report Information

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

Product Information

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

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Parotitis	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000067360	0	1988-01-26	1988-01-26	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
15 Months	Female			Unknown

Link / Duplicate Report Information

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

Product Information

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

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Parotitis	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000067361	0	1988-01-26	1988-01-26	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
15 Months	Female			Unknown

Link / Duplicate Report Information

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

Product Information

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

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Parotitis	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000067362	0	1988-01-26	1988-01-26	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
18 Months	Male			Unknown

Link / Duplicate Report Information

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

Product Information

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

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Parotitis	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000067363	0	1988-01-26	1988-01-26	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
1 Years	Male			Unknown

Link / Duplicate Report Information

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

Product Information

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

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Parotitis	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000067364	0	1988-01-26	1988-01-26	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
13 Months	Male			Unknown

Link / Duplicate Report Information

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

Product Information

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

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Parotitis	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000067365	0	1988-01-26	1988-01-26	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
14 Months	Male			Unknown

Link / Duplicate Report Information

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

Product Information

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

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Parotitis	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000067366	0	1988-01-26	1988-01-26	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
14 Months	Male			Unknown

Link / Duplicate Report Information

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

Product Information

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

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Parotitis	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000067367	0	1988-01-26	1988-01-26	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
14 Months	Male			Unknown

Link / Duplicate Report Information

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

Product Information

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

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Parotitis	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000067368	0	1988-01-26	1988-01-26	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
13 Months	Male			Unknown

Link / Duplicate Report Information

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

Product Information

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

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Parotitis	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000067370	0	1988-01-26	1988-01-26	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
14 Months	Female			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MEASLES MUMPS RUBELLA VIRUS VACCINE	Suspect	LIQUID SUBCUTANEOUS					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Parotitis	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000067372	0	1988-01-26	1988-01-26	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
15 Months	Male			Unknown

Link / Duplicate Report Information

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

Product Information

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

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Parotitis	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000103355	0	1970-01-26	1970-01-26	Hospital		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
16 Months	Female		13 Kilograms	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)
ATTENUVAX	Suspect	NOT SPECIFIED	Parenteral	0.5 mL			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Irritability	v.21.1	
Irritability	v.21.1	
Pyrexia	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000103386	0	1970-02-17	1970-02-17	Hospital		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
5 Years	Male	117 Centimetres	18 Kilograms	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)
MEASLES VACCINE	Suspect	POWDER FOR SOLUTION SUBCUTANEOUS	Subcutaneous			1.0 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Rash morbilliform	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000103437	0	1970-03-09	1970-03-09	Hospital		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
3 Years	Male			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
RUBEOVAX	Suspect	POWDER FOR SOLUTION SUBCUTANEOUS				1.0 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pallor	v.21.1	
Pyrexia	v.21.1	
Rash	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000103439	0	1970-03-09	1970-03-09	Hospital		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
20 Months	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)
RUBEOVAX	Suspect	POWDER FOR SOLUTION SUBCUTANEOUS				1.0 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pyrexia	v.21.1	
Rash erythematous	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000103528	0	1970-03-25	1970-03-25	Hospital		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
18 Months	Male			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
RUBEOVAX	Suspect	POWDER FOR SOLUTION SUBCUTANEOUS	Subcutaneous	0.5 mL		1.0 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pyrexia	v.21.1	
Rash	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000103606	0	1970-04-16	1970-04-16	Hospital		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
18 Months	Male			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
RUBEOVAX	Suspect	POWDER FOR SOLUTION SUBCUTANEOUS					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Injection site mass	v.21.1	
Pyrexia	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000103609	0	1970-04-17	1970-04-17	Hospital		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
5 Years	Female			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MEASLES VACCINE	Suspect	POWDER FOR SOLUTION SUBCUTANEOUS		0.5 mL		1.0 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Malaise	v.21.1	
Pyrexia	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000103832	0	1970-06-08	1970-06-08	Hospital		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
4 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)
RUBEOVAX	Suspect	POWDER FOR SOLUTION SUBCUTANEOUS					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Lymphadenopathy	v.21.1	
Pyrexia	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000103833	0	1970-06-09	1970-06-09	Hospital		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
3 Years	Female			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
RUBEOVAX	Suspect	POWDER FOR SOLUTION SUBCUTANEOUS					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Delirium	v.21.1	
Hyperpyrexia	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000104019	0	1970-02-16	1970-02-16			Spontaneous	Physician

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
2 Years	Female		10 Kilograms	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)
LIRUGEN	Suspect	POWDER FOR SOLUTION SUBCUTANEOUS	Subcutaneous	0.5 mL		1.0 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.21.1	
Decreased appetite	v.21.1	
Erythema	v.21.1	
Pyrexia	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000104073	0	1970-04-29	1970-04-29			Spontaneous	Physician

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
17 Months	Male			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
LIRUGEN	Suspect	POWDER FOR SOLUTION SUBCUTANEOUS					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Febrile convulsion	v.21.1	
Pyrexia	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000104538	0	1970-09-16	1970-09-16	Hospital		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
18 Months	Male			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MEASLES VACCINE	Suspect	POWDER FOR SOLUTION SUBCUTANEOUS					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pyrexia	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000104981	0	1970-01-14	1970-01-14	Hospital		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
29 Months	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)
LIRUGEN	Suspect	POWDER FOR SOLUTION SUBCUTANEOUS				1.0 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pyrexia	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000105254	0	1970-10-07	1970-10-07	Hospital		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
5 Years	Female		18 Kilograms	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)
MERUVAX	Suspect	POWDER FOR SOLUTION SUBCUTANEOUS	Subcutaneous			1.0 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.21.1	
Pyrexia	v.21.1	
Vascular headache	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000105296	0	1970-10-15	1970-10-15	Hospital		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
21 Months	Male			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
LIRUGEN	Suspect	POWDER FOR SOLUTION SUBCUTANEOUS					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Body temperature increased	v.21.1	
Seizure	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000106641	0	1971-03-01	1971-03-01	Hospital		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
1 Years	Male			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MEASLES VACCINE	Suspect	POWDER FOR SOLUTION SUBCUTANEOUS					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Febrile convulsion	v.21.1	
Rash	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000107586	0	1971-01-05	1971-01-05	Hospital		Spontaneous	

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

Patient Information

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

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MERUVAX	Suspect	POWDER FOR SOLUTION SUBCUTANEOUS	Subcutaneous	0.05 mL			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cyanosis	v.21.1	
Syncope	v.21.1	
Urticaria	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000110925	0	1972-02-07	1972-02-07			Spontaneous	Physician

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
20 Months	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)
ATTENUVAX	Suspect	NOT SPECIFIED	Parenteral			1.0 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Febrile convulsion	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000112556	0	1972-07-11	1972-07-11	MAH		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
7 Months	Male			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ATTENUVAX	Suspect	NOT SPECIFIED	Parenteral	0.5 mL			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Oedema	v.21.1	
Pyrexia	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000112623	0	1972-09-25	1972-09-25			Spontaneous	Physician

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
16 Months	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)
LIRUGEN	Suspect	POWDER FOR SOLUTION SUBCUTANEOUS					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Encephalitis	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000113486	0	1972-12-20	1972-12-20	Hospital		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
6 Years	Male		17 Kilograms	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)
M-R-VAX	Suspect	LIQUID SUBCUTANEOUS	Parenteral				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blepharitis	v.21.1	
Bronchospasm	v.21.1	
Hypertension	v.21.1	
Lethargy	v.21.1	
Oedema	v.21.1	
Pain	v.21.1	
Pruritus	v.21.1	
Pyrexia	v.21.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Rash maculo-papular	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000115155	0	1973-05-09	1973-05-09	Community		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
17 Months	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)
ATTENUVAX	Suspect	NOT SPECIFIED	Parenteral			12.0 Hour(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Loss of consciousness	v.21.1	
Pyrexia	v.21.1	
Seizure	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000115178	0	1972-12-27	1972-12-27	Community		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
5 Years	Male			Death

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)
ALLERGY INJECTION	Concomitant	NOT SPECIFIED					
M-R-VAX	Suspect	LIQUID SUBCUTANEOUS					

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Conjunctivitis	v.21.1	
Cyanosis	v.21.1	
Pyrexia	v.21.1	
Stupor	v.21.1	
Vomiting	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000117513	0	1998-04-14	1998-04-14	Community		Spontaneous	Pharmacist

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
1 Years	Female	72 Centimetres	11 Kilograms	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)
ACETAMINOPHEN	Drug used to treat AE	NOT SPECIFIED					
AMOXICILLIN	Suspect	SUSPENSION	Oral	1.0 Teaspoonful	3 every 1 Day(s)	4.0 Day(s)	
DIPHENHYDRAMINE	Drug used to treat AE	NOT SPECIFIED	Oral	20.0 Milligram			
MEASLES MUMPS RUBELLA VIRUS VACCINE	Suspect	LIQUID SUBCUTANEOUS	Intramuscular		Once		
PREDNISONE	Drug used to treat AE	SYRUP		5.0 Milligram			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Erythema multiforme	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000363003	0	2011-02-25	2011-02-25	MAH	201100714(0)	Spontaneous	Physician

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
21 Months	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)
MMR	Suspect	LIQUID SUBCUTANEOUS	Parenteral				Immunisation
PEDIACEL	Suspect	SUSPENSION INTRAMUSCULAR	Parenteral				Immunisation
PNEUMOCOCCAL VACCINE	Suspect	INJECTION	Parenteral				Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Febrile convulsion	v.21.1	
Hypotonic-hyporesponsive episode	v.21.1	
Loss of consciousness	v.21.1	
Respiratory arrest	v.21.1	
Seizure	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000363773	1	2011-03-09	2011-08-19	MAH	WAES1006USA04268B1	Spontaneous	Physician

Serious report?	Death:		Disability:		Congenital Anomaly:	Yes
Yes	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.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACYCLOVIR	Concomitant	NOT SPECIFIED	Unknown				
MEASLES MUMPS RUBELLA VIRUS VACCINE	Suspect	LIQUID SUBCUTANEOUS	Transplacental				Prophylaxis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Congenital hydronephrosis	v.21.1	
Foetal exposure during pregnancy	v.21.1	
Pyelocaliectasis	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000364314	0	2011-03-16	2011-03-16	Community		Spontaneous	Consumer Or Other Non Health Professional

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
13 Months	Male	78 Centimetres	9 Kilograms	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)
MEASLES MUMPS RUBELLA VIRUS VACCINE	Suspect	LIQUID SUBCUTANEOUS	Parenteral				Immunisation
MEASLES VACCINE	Suspect	POWDER FOR SOLUTION SUBCUTANEOUS	Parenteral				Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Diarrhoea	v.21.1	
Irritability	v.21.1	
Pyrexia	v.21.1	
Rash	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000366051	0	2011-04-08	2011-04-08	MAH	A0908408A	Spontaneous	Consumer Or Other Non Health Professional

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
12 Months	Unknown			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)
FLUVIRAL	Suspect	SUSPENSION INTRAMUSCULAR	Unknown				Prophylaxis
MMR	Suspect	LIQUID SUBCUTANEOUS	Unknown				Prophylaxis
NEISVAC-C	Suspect	SUSPENSION INTRAMUSCULAR	Unknown				Prophylaxis
VARILRIX	Suspect	POWDER FOR SOLUTION SUBCUTANEOUS	Unknown				Prophylaxis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Febrile convulsion	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000375833	1	2011-08-05	2012-02-03	MAH	A0938057A	Spontaneous	Other Health Professional

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
1 Years	Female			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MENJUGATE	Concomitant	POWDER FOR SUSPENSION INTRAMUSCULAR	Unknown				
PREVNAR 13	Concomitant	SUSPENSION INTRAMUSCULAR	Unknown				
PRIORIX-TETRA	Suspect	POWDER FOR SOLUTION INTRAMUSCULAR	Subcutaneous	0.5 mL	Total		Prophylaxis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Acne	v.21.1	
Arthralgia	v.21.1	
Crying	v.21.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Decreased interest	v.21.1	
Gait disturbance	v.21.1	
Hypophagia	v.21.1	
Injection site erythema	v.21.1	
Lethargy	v.21.1	
Mobility decreased	v.21.1	
Pyrexia	v.21.1	
Swelling	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000381184	0	2011-10-11	2011-10-11	Community		Spontaneous	Physician

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
13 Months	Male	76 Centimetres	23 Pounds	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)
MENJUGATE	Suspect	POWDER FOR SUSPENSION INTRAMUSCULAR	Intramuscular		Once		Immunisation
PRIORIX	Suspect	KIT	Intramuscular				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Urticaria	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000394411	0	2011-12-09	2011-12-09	MAH	A0956243A	Spontaneous	Consumer Or Other Non Health Professional

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Unknown			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)
MMR	Suspect		Parenteral			1.0 Day(s)	Immunisation
MMR	Suspect	LIQUID SUBCUTANEOUS	Parenteral			1.0 Day(s)	Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Measles	v.21.1	
Vaccination failure	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000394681	0	2011-12-12	2011-12-12	MAH	A0956124A	Spontaneous	Consumer Or Other Non Health Professional

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

Patient Information

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

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MENJUGATE	Suspect	POWDER FOR SUSPENSION INTRAMUSCULAR	Unknown				Prophylaxis
PRIORIX	Suspect	KIT	Unknown				Prophylaxis
SYNFLORIX	Suspect		Parenteral				Prophylaxis
SYNFLORIX	Suspect	SUSPENSION INTRAMUSCULAR	Parenteral				Prophylaxis
VARIVAX III	Suspect	POWDER FOR SOLUTION SUBCUTANEOUS	Unknown				Prophylaxis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Autism spectrum disorder	v.21.1	
Dissociation	v.21.1	
Malnutrition	v.21.1	
Sleep disorder	v.21.1	
Speech disorder	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000405161	2	2012-01-24	2012-02-09	MAH	2012014501	Spontaneous	Consumer Or Other Non Health Professional

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
1 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Duplicate	000411585
Duplicate	000411594

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
INFLUENZA VACCINE	Suspect	NOT SPECIFIED	Parenteral	1.0 Dosage forms	Once		Immunisation
MEASLES MUMPS RUBELLA VIRUS VACCINE	Suspect	LIQUID SUBCUTANEOUS	Parenteral	1.0 Dosage forms	Once		Immunisation
PREVNAR SINGLE DOSE PRE-FILLED SYRINGES AND VIALS	Suspect	SUSPENSION INTRAMUSCULAR	Parenteral	1.0 Dosage forms	Once		Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Autism spectrum disorder	v.21.1	
Brain injury	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000411549	0	2012-02-14	2012-02-14	MAH	PHHY2012CA011067	Spontaneous	Consumer Or Other Non Health Professional

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Duplicate	000405179

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
INFLUENZA VACCINE	Suspect	NOT SPECIFIED	Parenteral	1.0 Dosage forms	Total		Immunisation
MMR	Suspect	LIQUID SUBCUTANEOUS	Parenteral				Product used for unknown indication
PREVNAR SINGLE DOSE PRE-FILLED SYRINGES AND VIALS	Suspect	SUSPENSION INTRAMUSCULAR	Parenteral				Product used for unknown indication

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Autism spectrum disorder	v.21.1	
Brain injury	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000411585	0	2012-02-14	2012-02-14	MAH	1202USA01182	Spontaneous	Consumer Or Other Non Health Professional

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
1 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Duplicate	000411594
Duplicate	000405161

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
INFLUENZA VACCINE	Suspect	NOT SPECIFIED	Parenteral				Immunisation
MMR	Suspect	LIQUID SUBCUTANEOUS	Parenteral				Immunisation
PREVNAR SINGLE DOSE PRE-FILLED SYRINGES AND VIALS	Suspect	SUSPENSION INTRAMUSCULAR	Parenteral				Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Autism spectrum disorder	v.21.1	
Brain injury	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000411594	0	2012-02-14	2012-02-14	MAH	PHHY2012CA011066	Spontaneous	Consumer Or Other Non Health Professional

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Duplicate	000411585
Duplicate	000405161

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
INFLUENZA VACCINE	Suspect	NOT SPECIFIED	Parenteral	1.0 Dosage forms	Total		Immunisation
MMR	Suspect	LIQUID SUBCUTANEOUS	Parenteral				Immunisation
PREVNAR SINGLE DOSE PRE-FILLED SYRINGES AND VIALS	Suspect	SUSPENSION INTRAMUSCULAR	Parenteral				Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Autism spectrum disorder	v.21.1	
Brain injury	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000414960	1	2012-02-28	2012-03-01	MAH	A0966772A	Spontaneous	Physician

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
4 Years	Male			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PEDIACEL	Concomitant	SUSPENSION INTRAMUSCULAR					
PRIORIX	Suspect	KIT	Subcutaneous	0.5 mL	Total	1.0 Day(s)	Prophylaxis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Immune thrombocytopenic purpura	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000415042	0	2012-02-28	2012-02-28	MAH	201200556(0)	Spontaneous	Other Health Professional

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
7 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)
MMR	Suspect	LIQUID SUBCUTANEOUS	Subcutaneous				Immunisation
QUADRACEL	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.5 mL			Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cellulitis	v.21.1	10 Day(s)
Injection site erythema	v.21.1	
Injection site induration	v.21.1	
Injection site reaction	v.21.1	
Injection site swelling	v.21.1	
Injection site warmth	v.21.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Product administered to patient of inappropriate age	v.21.1	
Pyrexia	v.21.1	
Vaccination site discharge	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000430459	0	2012-04-20	2012-04-20	MAH	1204USA01297	Spontaneous	Other Health Professional

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
18 Months	Male			Not recovered/not resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Duplicate	000433535
Duplicate	000431260

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MEASLES MUMPS RUBELLA VIRUS VACCINE	Suspect	LIQUID SUBCUTANEOUS	Parenteral	0.5 Milligram/Milliliters	Total		Prophylaxis
PEDIACEL	Suspect	SUSPENSION INTRAMUSCULAR	Parenteral				Prophylaxis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cellulitis	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000431252	0	2012-04-24	2012-04-24	MAH	1204USA02508	Spontaneous	Consumer Or Other Non Health Professional

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
6 Years	Male			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MEASLES MUMPS RUBELLA VIRUS VACCINE	Suspect	LIQUID SUBCUTANEOUS	Parenteral				Immunisation
VARICELLA VACCINE	Suspect	NOT SPECIFIED	Parenteral				Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cognitive disorder	v.21.1	
Febrile convulsion	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000431255	0	2012-04-24	2012-04-24	MAH	1204USA02486	Spontaneous	Consumer Or Other Non Health Professional

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
6 Years	Male			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MEASLES MUMPS RUBELLA VIRUS VACCINE	Suspect	LIQUID SUBCUTANEOUS	Parenteral				Immunisation
VARICELLA VACCINE	Suspect	NOT SPECIFIED	Parenteral				Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cognitive disorder	v.21.1	
Febrile convulsion	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000433535	0	2012-05-01	2012-05-01	MAH	201204242	Spontaneous	Other Health Professional

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
18 Months	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Duplicate	000431260
Duplicate	000430459

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MMR	Suspect	LIQUID SUBCUTANEOUS	Parenteral	0.5 mL	Total		Immunisation
PEDIACEL	Suspect	SUSPENSION INTRAMUSCULAR	Parenteral		Total		Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cellulitis	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000479974	0	2012-11-23	2012-11-23	Community		Spontaneous	Other Health Professional

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
14 Months	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)
M-M-R* II	Suspect	POWDER FOR SOLUTION SUBCUTANEOUS	Sublingual	0.5 Milligram	Once		Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Aphasia	v.21.1	
Autism spectrum disorder	v.21.1	
Measles	v.21.1	
Mood altered	v.21.1	
Motor developmental delay	v.21.1	
Personality change	v.21.1	
Poor feeding infant	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000485357	0	2012-12-18	2012-12-18	Community		Spontaneous	Physician

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
12 Months	Male	76 Centimetres	10 Kilograms	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)
M-M-R* II	Suspect	POWDER FOR SOLUTION SUBCUTANEOUS	Subcutaneous	0.5 mL	Once		Immunisation
MENJUGATE	Suspect	POWDER FOR SUSPENSION INTRAMUSCULAR	Intramuscular	0.5 mL	Once		Immunisation
PREVNAR 13	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.5 mL	Once		Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pneumonia	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000486997	0	2012-12-06	2012-12-06	MAH	1211CAN012789	Spontaneous	Consumer Or Other Non Health Professional

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
26 Months	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)
M-M-R* II	Suspect	POWDER FOR SOLUTION SUBCUTANEOUS	Subcutaneous				Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Aggression	v.21.1	
Agitation	v.21.1	
Anger	v.21.1	
Emotional disorder	v.21.1	
Food aversion	v.21.1	
Insomnia	v.21.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Irritability	v.21.1	
Nervousness	v.21.1	
Rash erythematous	v.21.1	
Speech disorder	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000497700	0	2013-01-29	2013-01-29	MAH	A1008886A	Spontaneous	Pharmacist

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
12 Months	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)
TRIVIRIX	Suspect	LIQUID SUBCUTANEOUS	Unknown			1.0 Day(s)	Prophylaxis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asphyxia	v.21.1	
Cyanosis	v.21.1	
Febrile convulsion	v.21.1	
Pyrexia	v.21.1	
Skin discolouration	v.21.1	
Vaccination complication	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000507682	1	2013-03-11	2013-03-26	MAH	A1015021A	Spontaneous	Physician

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
13 Months	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)
PRIORIX-TETRA	Suspect	POWDER FOR SOLUTION INTRAMUSCULAR	Unknown	0.5 mL			Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Ear infection	v.21.1	
Measles	v.21.1	
Pyrexia	v.21.1	
Rash maculo-papular	v.21.1	
Varicella	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000538516	0	2013-07-03	2013-07-03	MAH	B0904467A	Published	Consumer Or Other Non Health Professional

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
5 Years	Male			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PRIORIX	Suspect	KIT	Unknown				Prophylaxis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Conjunctivitis	v.21.1	
Cough	v.21.1	
Measles	v.21.1	
Pyrexia	v.21.1	
Rash maculo-papular	v.21.1	
Rhinitis	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000569377	0	2013-11-07	2013-11-07	MAH	2013SA112809	Spontaneous	Other Health Professional

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
5 Years	Male			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MMR	Suspect	LIQUID SUBCUTANEOUS	Unknown				Immunisation
QUADRACEL	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.5 mL	Once	1.0 Once	Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Vaccination site cellulitis	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000570304	0	2013-11-14	2013-11-14	MAH	1310USA012271	Spontaneous	Physician

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
1 Years	Male			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
M-M-R* II	Suspect	POWDER FOR SOLUTION SUBCUTANEOUS	Unknown				Prophylaxis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.21.1	
Asthma	v.21.1	
Hypersensitivity	v.21.1	
Mumps antibody test negative	v.21.1	
Pulmonary congestion	v.21.1	
Urticaria	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000573278	0	2013-11-21	2013-11-21	MAH	A1039985A	Spontaneous	Other Health Professional

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

Patient Information

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

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PRIORIX-TETRA	Suspect	POWDER FOR SOLUTION INTRAMUSCULAR	Unknown	0.5 mL			Prophylaxis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Thrombocytopenia	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000578578	0	2013-12-17	2013-12-17	MAH	2013BAX049753	Spontaneous	Other Health Professional

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
13 Months	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)
NEISVAC-C	Suspect	SUSPENSION INTRAMUSCULAR	Unknown				Immunisation
PREVNAR SINGLE DOSE PRE-FILLED SYRINGES AND VIALS	Suspect	SUSPENSION INTRAMUSCULAR	Unknown				Immunisation
PRIORIX-TETRA	Suspect	POWDER FOR SOLUTION INTRAMUSCULAR	Unknown				Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cough	v.21.1	
Diarrhoea	v.21.1	
Irritability	v.21.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Product administration error	v.21.1	
Pyrexia	v.21.1	1 Day(s)
Rhinorrhoea	v.21.1	
Viral infection	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000581363	0	2014-01-02	2014-01-02	MAH	B0955432A	Published	Other Health Professional

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
2 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)
MENINGOCOCCAL VACCINES	Concomitant	NOT SPECIFIED					
PNEUMOCOCCAL VACCINE	Concomitant	INJECTION					
PRIORIX	Suspect	KIT	Unknown			1.0 Day(s)	Prophylaxis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Conjunctivitis	v.21.1	
Measles	v.21.1	
Pyrexia	v.21.1	
Rash macular	v.21.1	
Rhinorrhoea	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000593092	0	2014-03-12	2014-03-12	MAH	2014SA030335	Spontaneous	Consumer Or Other Non Health Professional

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
19 Months	Female			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MENINGOCOCCAL VACCINES	Suspect	NOT SPECIFIED	Unknown				Immunisation
PEDIACEL	Suspect	SUSPENSION INTRAMUSCULAR	Unknown				Immunisation
PNEUMOCOCCAL VACCINE	Suspect	INJECTION	Unknown				Immunisation
PRIORIX-TETRA	Suspect	POWDER FOR SOLUTION INTRAMUSCULAR	Unknown				Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Incomplete course of vaccination	v.21.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pertussis	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000593247	2	2014-03-12	2014-05-07	MAH	A1063755A	Unknown	Consumer Or Other Non Health Professional

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
12 Months	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Duplicate	000594722

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MENINGOCOCCAL VACCINES	Suspect	NOT SPECIFIED	Unknown			1.0 Day(s)	Prophylaxis
PEDIACEL	Suspect	SUSPENSION INTRAMUSCULAR	Unknown			1.0 Day(s)	Prophylaxis
PREVNAR 13	Suspect	SUSPENSION INTRAMUSCULAR	Unknown			1.0 Day(s)	Prophylaxis
PRIORIX-TETRA	Suspect	POWDER FOR SOLUTION INTRAMUSCULAR	Unknown			1.0 Day(s)	Prophylaxis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pertussis	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000594722	1	2014-03-17	2014-05-06	MAH	A1063812A	Spontaneous	Physician

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
1 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Duplicate	000593247

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MENINGOCOCCAL VACCINES	Suspect	NOT SPECIFIED	Unknown				Prophylaxis
PEDIACEL	Suspect	SUSPENSION INTRAMUSCULAR	Unknown				Prophylaxis
PREVNAR 13	Suspect	SUSPENSION INTRAMUSCULAR	Unknown				Prophylaxis
PRIORIX-TETRA	Suspect	POWDER FOR SOLUTION INTRAMUSCULAR	Unknown				Prophylaxis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pertussis	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000600134	0	2014-04-09	2014-04-09	Community		Spontaneous	Pharmacist

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
1 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Duplicate	E2B_00168660
Duplicate	E2B_02311283

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
M-M-R* II	Suspect	POWDER FOR SOLUTION SUBCUTANEOUS	Subcutaneous	0.5 Milligram	Once		Immunisation
MENJUGATE	Suspect	POWDER FOR SUSPENSION INTRAMUSCULAR	Intramuscular	0.5 Milligram	Once		Immunisation
PREVNAR 13	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.5 Milligram	Once		Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Body temperature increased	v.21.1	
Crying	v.21.1	4 Day(s)
Irritability	v.21.1	4 Day(s)

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000624117	0	2014-09-04	2014-09-04	Community		Spontaneous	Physician

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
1 Years	Male		9 Kilograms	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Duplicate	E2B_00235106
Duplicate	E2B_02306421

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
M-M-R* II	Suspect	POWDER FOR SOLUTION SUBCUTANEOUS	Subcutaneous	0.5 mL	Once		
MENJUGATE	Suspect	POWDER FOR SUSPENSION INTRAMUSCULAR	Intramuscular	0.5 mL	Once		Immunisation
PREVNAR SINGLE DOSE PRE-FILLED SYRINGES AND VIALS	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.5 mL	Once		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dermatitis	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000628633	0	2014-10-08	2014-10-08	Community		Spontaneous	Physician

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
4 Years	Female	110 Centimetres	19 Kilograms	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)
ADACEL-POLIO	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.5 mL	Total		Immunisation
MMR	Suspect	LIQUID SUBCUTANEOUS	Subcutaneous	0.5 mL	Total		Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Joint swelling	v.21.1	
Rash	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000631224	0	2014-11-10	2014-11-10	Hospital		Spontaneous	Physician

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
13 Months	Male		10 Pounds	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Duplicate	E2B_02311198
Duplicate	E2B_00330016

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MENJUGATE	Suspect	POWDER FOR SUSPENSION INTRAMUSCULAR	Intramuscular	1.0 Dosage forms	Once		Immunisation
PREVNAR SINGLE DOSE PRE-FILLED SYRINGES AND VIALS	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	1.0 Dosage forms	Once		Immunisation
PRIORIX	Suspect	KIT	Subcutaneous	1.0 Dosage forms	Total		Immunisation
VAXIGRIP	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	1.0 Dosage forms	Once		Influenza immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Irritability	v.21.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pyrexia	v.21.1	
Vaccination site pain	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000646635	0	2015-03-15	2015-03-15	Hospital		Spontaneous	Pharmacist

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
4 Years	Male		22 Kilograms	Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACETAMINOPHEN	Concomitant	NOT SPECIFIED					
DIPHTHERIA AND TETANUS TOXOIDS WITH PERTUSSIS VACCINE ADSORBED	Concomitant	LIQUID INTRAMUSCULAR	Intramuscular				
INFLUENZA VACCINE	Concomitant	NOT SPECIFIED	Intramuscular				
MEASLES MUMPS RUBELLA VIRUS VACCINE	Suspect	LIQUID SUBCUTANEOUS	Intramuscular				Immunisation
VARICELLA VACCINE	Suspect	NOT SPECIFIED	Intramuscular				Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cough	v.21.1	
Decreased appetite	v.21.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Febrile convulsion	v.21.1	
Vomiting	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000647275	0	2015-03-19	2015-03-19	Community	2014ADR039	Spontaneous	Physician

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
1 Years	Female		10 Kilograms	Death

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)
INFLUENZA VACCINE	Suspect	NOT SPECIFIED	Unknown		Once		Immunisation
MMR	Suspect	LIQUID SUBCUTANEOUS	Unknown		Once		Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Death	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000663030	0	2015-09-02	2015-09-02	Community		Spontaneous	Other Health Professional

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
18 Months	Male	91 Centimetres	14 Kilograms	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)
MEASLES MUMPS RUBELLA VIRUS VACCINE	Concomitant	LIQUID SUBCUTANEOUS					
MEASLES MUMPS RUBELLA VIRUS VACCINE	Suspect	LIQUID SUBCUTANEOUS	Intramuscular		Once		Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Rash morbilliform	v.21.1	
Rash vesicular	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000665499	0	2015-10-06	2015-10-06	Community		Spontaneous	Physician

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
5 Years	Male	107 Centimetres	15 Kilograms	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)
ADACEL-POLIO	Suspect	SUSPENSION INTRAMUSCULAR					Immunisation
PRIORIX-TETRA	Suspect	POWDER FOR SOLUTION INTRAMUSCULAR	Intramuscular				Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.21.1	
Bronchospasm	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000665937	1	2015-10-11	2015-11-04	Community		Spontaneous	Physician

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
12 Months	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)
MMRV	Suspect	NOT SPECIFIED	Unknown				Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Malaise	v.21.1	
Rash morbilliform	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000676417	0	2016-04-06	2016-04-06	Community		Spontaneous	Physician

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
12 Months	Female	77 Centimetres	10 Kilograms	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)
AMOXICILLIN	Concomitant	NOT SPECIFIED					
M-M-R* II	Suspect	POWDER FOR SOLUTION SUBCUTANEOUS	Subcutaneous	0.5 mL	Once		Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Rash morbilliform	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000679333	0	2016-05-24	2016-05-24	Community		Spontaneous	Physician

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
4 Years	Female	106 Centimetres	18 Kilograms	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)
INFANRIX-IPV PRE-FILLED SYRINGES	Concomitant	SUSPENSION INTRAMUSCULAR					
PRIORIX-TETRA	Suspect	POWDER FOR SOLUTION INTRAMUSCULAR		0.5 Milligram			Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Rash pruritic	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000689271	0	2016-12-05	2016-12-05	Community		Spontaneous	Consumer Or Other Non Health Professional

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

Patient Information

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

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
M-M-R* II	Suspect	POWDER FOR SOLUTION SUBCUTANEOUS			Once		Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abnormal behaviour	v.21.1	
Aphasia	v.21.1	
Apraxia	v.21.1	
Brain injury	v.21.1	
Condition aggravated	v.21.1	
Decreased eye contact	v.21.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Depressed level of consciousness	v.21.1	
Developmental delay	v.21.1	
Dyskinesia	v.21.1	
Dysphonia	v.21.1	
Eye movement disorder	v.21.1	
Gaze palsy	v.21.1	
Hallucination	v.21.1	
Nystagmus	v.21.1	
Petit mal epilepsy	v.21.1	
Speech disorder	v.21.1	
Speech disorder developmental	v.21.1	
Speech sound disorder	v.21.1	
Toe walking	v.21.1	
Tongue disorder	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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
000691183	0	2017-01-18	2017-01-18	Community		Spontaneous	Consumer Or Other Non Health Professional

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
1 Years	Male	30 Inches	28 Pounds	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)
MMR	Suspect	LIQUID SUBCUTANEOUS	Intramuscular				Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.21.1	
Hospitalisation	v.21.1	
Seizure	v.21.1	
Vomiting	v.21.1	

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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
000700332	0	2017-07-19	2017-07-19	Community		Spontaneous	Consumer Or Other Non Health Professional

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
18 Months	Male			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
INFANRIX HEXA	Concomitant	SUSPENSION INTRAMUSCULAR					
PROQUAD	Suspect	POWDER FOR SOLUTION SUBCUTANEOUS	Intramuscular		Once		Varicella immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Diarrhoea	v.21.1	
Listless	v.21.1	
Pain	v.21.1	
Pyrexia	v.21.1	
Rash pruritic	v.21.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Rash vesicular	v.21.1	
Varicella post vaccine	v.21.1	

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000702090	0	2017-08-30	2017-08-30	Community		Spontaneous	Physician

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
4 Years	Female	113 Centimetres	29 Kilograms	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)
ADACEL-POLIO	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.5 mL			Immunisation
PROQUAD	Suspect	POWDER FOR SOLUTION SUBCUTANEOUS	Subcutaneous	0.5 mL			Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Acute disseminated encephalomyelitis	v.21.1	
Encephalitis	v.21.1	
Endotracheal intubation	v.21.1	
Febrile convulsion	v.21.1	
Pyrexia	v.21.1	

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000715486	0	2018-07-09	2018-07-09	Community		Spontaneous	Physician

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
4 Years	Female	106 Centimetres	19 Pounds	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)
ADACEL-POLIO	Concomitant	SUSPENSION INTRAMUSCULAR					
PROQUAD	Suspect	POWDER FOR SOLUTION SUBCUTANEOUS	Subcutaneous	0.5 mL	Once		Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Injection site erythema	v.21.1	
Mass	v.21.1	

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Report Information

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000715985	0	2018-07-20	2018-07-20	Community		Spontaneous	Physician

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
4 Years	Male	107 Centimetres	15 Kilograms	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)
ADACEL POLIO	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.5 mL			Immunisation
PRIORIX TETRA	Suspect	POWDER FOR SOLUTION INTRAMUSCULAR	Subcutaneous	0.5 mL			Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Unresponsive to stimuli	v.21.1	

Canada Vigilance
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Report Information

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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
000716559	0	2018-08-09	2018-08-09	Community		Spontaneous	Physician

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
12 Months	Female	77 Centimetres	9 Kilograms	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)
MMR	Suspect	LIQUID SUBCUTANEOUS	Parenteral				Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Eyelid ptosis	v.21.1	
IIIrd nerve paralysis	v.21.1	
Movement disorder	v.21.1	
Pyrexia	v.21.1	

Canada Vigilance
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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
000718882	0	2018-10-11	2018-10-11	Community		Spontaneous	Physician

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
1 Years	Female		9 Kilograms	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)
BENADRYL	Concomitant	NOT SPECIFIED					
BETADERM	Concomitant	NOT SPECIFIED					
M-M-R II	Suspect	POWDER FOR SOLUTION SUBCUTANEOUS	Intramuscular		Once		
MENJUGATE LIQUID 0.5 ML SINGLE DOSE PREFILLED SYRINGES	Suspect	SUSPENSION INTRAMUSCULAR			Once		
PREVNAR 13	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Febrile convulsion	v.21.1	
Movement disorder	v.21.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Tonic clonic movements	v.21.1	

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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
E2B_00168660	0	2014-10-27	2014-10-27	MAH	PHHY2014CA138813	Spontaneous	Other Health Professional

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
1 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Duplicate	E2B_02311283
Duplicate	000600134

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
M-M-R* II	Suspect	POWDER FOR SOLUTION SUBCUTANEOUS	Subcutaneous	0.5 mL			Immunisation
MENJUGATE	Suspect	POWDER FOR SUSPENSION INTRAMUSCULAR	Intramuscular	0.5 mL			Immunisation
PREVNAR 13	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.5 mL			Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Body temperature increased	v.21.1	
Crying	v.21.1	4 Day(s)

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Irritability	v.21.1	4 Day(s)

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Report Information

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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
E2B_00235106	0	2015-01-29	2015-01-29	MAH	PHHY2015CA009985	Spontaneous	Other Health Professional

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
1 Years	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Duplicate	000624117
Duplicate	E2B_02306421

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
M-M-R* II	Suspect	POWDER FOR SOLUTION SUBCUTANEOUS	Subcutaneous	0.5 mL			Immunisation
MENJUGATE	Suspect	POWDER FOR SUSPENSION INTRAMUSCULAR	Intramuscular	0.5 mL			Immunisation
PREVNAR SINGLE DOSE PRE-FILLED SYRINGES AND VIALS	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.5 mL			Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dermatitis	v.21.1	

Canada Vigilance
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E2B_00276855	0	2015-03-13	2015-03-13	MAH	1503CAN005703	Spontaneous	Consumer Or Other Non Health Professional

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

Patient Information

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

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
M-M-R* II	Suspect	POWDER FOR SOLUTION SUBCUTANEOUS	Unknown				Prophylaxis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Aphasia	v.21.1	
Autism spectrum disorder	v.21.1	
Brain injury	v.21.1	
Cognitive disorder	v.21.1	
Vaccination failure	v.21.1	

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E2B_00330016	0	2015-04-30	2015-04-30	MAH	PHHY2015CA049374	Spontaneous	Other Health Professional

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
13 Months	Male		10 Kilograms	Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Duplicate	000631224

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MENJUGATE INN	Suspect	NOT SPECIFIED	Intramuscular	1.0 Dosage forms			Immunisation
PREVNAR 13	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	1.0 Dosage forms			Immunisation
PRIORIX	Suspect	SUSPENSION INTRAMUSCULAR	Subcutaneous	1.0 Dosage forms			Immunisation
VAXIGRIP	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	1.0 Dosage forms			Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Irritability	v.21.1	
Pyrexia	v.21.1	
Vaccination site pain	v.21.1	

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E2B_00355781	0	2015-05-26	2015-05-26	MAH	1505CAN012360	Study	Consumer Or Other Non Health Professional

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
12 Months	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)
MEASLES VIRUS VACCINE LIVE ATTENUATED/MUMPS VACCINE/RUBELLA VACCINE	Suspect		Subcutaneous	1.0 Dosage forms	1 every 1 Day(s)		
NEISVAC-C	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	1.0 Dosage forms	1 every 1 Day(s)		Product used for unknown indication
PREVNAR 13	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular				Prophylaxis
VARIVAX	Suspect	POWDER FOR SOLUTION SUBCUTANEOUS	Subcutaneous	1.0 Dosage forms			Varicella

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pyrexia	v.21.1	22 Day(s)

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E2B_00603503	0	2015-12-30	2015-12-30	MAH	2014BAX012913	Spontaneous	Consumer Or Other Non Health Professional

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
12 Months	Female			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
DIPHTHERIA TOXOID ADSORBED/HAEMOPHILUS INFLUENZAE VACCINE/PERTUSSIS VACCINE/POLIO VACCINE/TETANUS VACCINE	Suspect		Unknown				Immunisation
MEASLES/MUMPS/RUBELLA VACCINE	Suspect		Unknown				Immunisation
MENINGOCOCCAL POLYSACCHARIDE VACCINE GRP C	Suspect		Unknown				Immunisation
MENINGOCOCCAL VACCINE	Suspect		Unknown				Immunisation

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
PREVNAR 13	Suspect	SUSPENSION INTRAMUSCULAR	Unknown				Immunisation
VARICELLA VACCINE	Suspect	NOT SPECIFIED	Unknown				Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pertussis	v.21.1	

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E2B_01120753	0	2017-01-05	2017-01-05	Clinical Study	CA2016GSK192489	Published	Physician

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
5 Years				Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MEASLES VACCINE VIRUS LIVE ATTENUATED/RUBELLA VACCINE/MUMPS VACCINE	Suspect		Unknown				Prophylaxis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Febrile convulsion	v.21.1	

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E2B_01845217	0	2018-04-16	2018-04-16	MAH	1804CAN006211	Spontaneous	Consumer Or Other Non Health Professional

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
1 Years	Male			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
M-M-R II	Suspect	POWDER FOR SOLUTION SUBCUTANEOUS	Unknown			1.0 Month(s)	Prophylaxis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Autism spectrum disorder	v.21.1	
Pica	v.21.1	
Viral infection	v.21.1	

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E2B_02063166	0	2018-08-14	2018-08-14	MAH	US2018GSK013137	Published	

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

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.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
DIPHTHERIA TOXOID/TETANUS TOXOID/PERTUSSIS TOXOID/FILAMENTOUS HAEMAGGLUTININ/PERTACTIN/INACTIVATED POLIOVIRUS TYPE I/INACTIVATE	Suspect		Unknown				Prophylaxis
HEPATITIS A VACCINE, INACTIVATED/HEPATITIS B SURFACE ANTIGEN (RECOMBINANT)	Suspect		Unknown				Prophylaxis
HEPATITIS A VACCINE, INACTIVATED/HEPATITIS B SURFACE ANTIGEN (RECOMBINANT)	Suspect	Solution for injection	Unknown				Prophylaxis

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MEASLES VIRUS VACCINE LIVE ATTENUATED/MUMPS VACCINE/RUBELLA VACCINES/ZOSTAVAX,VARILRIX III	Suspect		Unknown				Prophylaxis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Eosinophilic cellulitis	v.21.1	
Eosinophilic cellulitis	v.21.1	
Eosinophilic cellulitis	v.21.1	
Erythema	v.21.1	
Erythema	v.21.1	
Erythema	v.21.1	
Oedema	v.21.1	
Oedema	v.21.1	
Oedema	v.21.1	
Pruritus	v.21.1	
Pruritus	v.21.1	
Pruritus	v.21.1	
Rash vesicular	v.21.1	
Rash vesicular	v.21.1	
Rash vesicular	v.21.1	
Skin ulcer	v.21.1	
Skin ulcer	v.21.1	
Skin ulcer	v.21.1	

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E2B_02073840	1	2018-08-20	2018-08-28	MAH	2018SA226582	Published	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
3 Years	Male			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
DIPHTHERIA TOXOID ADSORBED/PERTUSSIS VACCINE/TETANUS VACCINE	Suspect		Unknown				Immunisation
MEASLES VIRUS VACCINE LIVE ATTENUATED/MUMPS VACCINE/RUBELLA VACCINE	Suspect		Unknown				Immunisation
POLIO VACCINE	Suspect		Unknown				Immunisation

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blister	v.21.1	
Eosinophilic cellulitis	v.21.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Erythema	v.21.1	
Pain	v.21.1	
Pruritus	v.21.1	
Rash vesicular	v.21.1	
Tenderness	v.21.1	
Ulcer	v.21.1	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2019-03-07 - 01:58:06 PM
Initial Received Date: 1970-01-01 to 2018-11-30
Latest Received Date: N/A
Total Number of Reports: 237 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_02187575	0	2018-10-24	2018-10-24	MAH	CA2018GSK192061	Published	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
1 Years	Male			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MEASLES VIRUS VACCINE LIVE ATTENUATED/MUMPS VACCINE/RUBELLA VACCINES	Suspect		Unknown				Prophylaxis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain	v.21.1	
Aphthous ulcer	v.21.1	
Bronchiolitis	v.21.1	
Decreased appetite	v.21.1	
Irritability	v.21.1	
Lymphadenitis	v.21.1	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Lymphadenopathy	v.21.1	
Measles	v.21.1	
Mouth ulceration	v.21.1	
Musculoskeletal pain	v.21.1	
Oropharyngeal pain	v.21.1	
Pharyngitis	v.21.1	
Pyrexia	v.21.1	
Swelling	v.21.1	
Vaccination failure	v.21.1	