Health Canada Santé Canada

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2019-03-07 - 02:42:47 PM
Initial Received Date:	1965-01-01 to 2018-11-30
Latest Received Date:	N/A
Total Number of Reports:	9 Report(s)

Brand Name/Active Ingredient: measles
Search Date Criteria: 1965-01-01 to 2018-11-30
Reaction Term(s): All/Tous
Serious report?: Yes
Type of Report: All
Source of Report: All
Gender: All
Report Outcome: Death
Age: All

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

Canada

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Report Information

***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
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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000002700	0	1974-04-09	1974-04-09	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
	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)
ATTENUVAX	Suspect	NOT SPECIFIED	Parenteral				

Adverse Reaction Term Information

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

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000030242	0	1981-06-01	1981-06-01	Other		Spontaneous	

Serious report?	Death:	Disability:	Congenital Anomaly:
Yes	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	

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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	

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000091883	0	1966-03-03	1966-03-03			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
4 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)
MEASLES VACCINE	Suspect	POWDER FOR SOLUTION SUBCUTANEOUS	Parenteral	1.0 mL			
QUAD VACCINE	Suspect	NOT SPECIFIED	Parenteral	1.0 mL			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Application site reaction	v.21.1	
Pneumonitis	v.21.1	

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000097310	0	1967-11-17	1967-11-17	Hospital		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
11 Months	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)
MEASLES VACCINE	Suspect	POWDER FOR SOLUTION SUBCUTANEOUS	Intramuscular				

Adverse Reaction Term Information

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

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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	

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000647275	0	2015-03-19	2015-03-19	Community	2014ADR039	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
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	

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E2B_00515150	0	2015-10-16	2015-10-16	MAH	1510CAN007141	Spontaneous	Consumer Or Other Non Health Professional

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
	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)
M-M-R* II	Suspect	POWDER FOR SOLUTION SUBCUTANEOUS	Unknown				Prophylaxis

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Sudden infant death syndrome	v.21.1	
Urticaria	v.21.1	