

Health Canada Santé Canada

# Canada Vigilance Summary of Reported Adverse Reactions

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



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Canada Vigilance
Summary of Reported Adverse Reactions

Adverse Reaction Report Number	Latest AE		Initial Recei	ved Date	Latest	Received Date	Sourc	e of Report	Auth	arket orization LER Number	Type of Report	Reporter Type
000002399	C	)	1974-0	3-14	19	74-03-14		MAH			Spontaneous	
Serious re	eport?				Death:			Disabilit	y:	Congenital Anomaly:		
Yes			L	ife Threate	ening:		Н	ospitalizatio	n: Yes	Other Med	dically Important Co	onditions:
Patient Information	n											
Age	Gender		Height	V	Veight		Report	Outcome				
12 Months	Female						D	eath				
Link / Duplicate R	eport Infor	mation										
	Record	I Туре				Link AER	** Numb	er				
No duplicate or linl	ced report.											
Product Informati	on											
Product Desc	ription	Health Pr	oduct Role	Dosag	e Form	Route Administ		Dose	Fr	equency	Therapy Duration	Indication(s)
ATTENUVAX		Sus	spect	NOT SP	ECIFIED	Parent	eral					

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 Informat	ion	**AE	R = Adverse F	Reaction Re	eport							
Adverse Reaction Repo Number	T	ER Version mber	Initial Rece	ived Date	Latest Rece	eived Date	Sourc	e of Report	Auth	larket orization AER Number	Type of Report	Reporter Type
000002700		0	1974-0	14-09	1974-0	)4-09	Co	mmunity			Spontaneous	
Serious	report?				Death:			Disabilit	y:		Congenital	Anomaly:
Ye	es			Life Threat	tening:		Н	ospitalizatio	n: Yes			
Patient Informa	tion											
Age	Gender	,	Height	1	Weight		Report	Outcome				
	Male						D	eath				
Link / Duplicate	Report Info	rmation										
	Reco	rd Type				Link AER*	* Numb	er				
No duplicate or li	nked report.											
Product Informa	ation											
Product Des	cription	Health Pr	roduct Role	Dosaç	ge Form	Route Administr		Dose	Fr	equency	Therapy Duration	Indication(s)
ATTENUVAX		Su	spect	NOT SF	PECIFIED	Parente	eral					
Adverse Reaction	on Term											
	Ad	verse Read	ction Term(s)			Me	dDRA	Version			Reaction Duration	
Diarrhoea	_						v.21					
Gastroenteritis	7						v.21	.1				

v.21.1

Pyrexia

Report Runtime: Initial Received Date: Latest Received Date: Total Number of Reports: 2019-03-07 - 02:42:47 PM 1965-01-01 to 2018-11-30

9 Report(s)

	Summary of Reported Adverse Reactions
Report Information	**AER = Adverse Reaction Report

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date		Market Authorization Holder AER Number	Type of Report	Reporter Type
000030242	0	1981-06-01	1981-06-01	Other		Spontaneous	
Sorious roport?			Death: Voc	Dicabilit	v.	Congenital	Anomaly

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

Patient Informa	tion				
Age Gender		Height	Weight	Report Outcome	
2 Years	Female			Death	

Link / Duplicate Report Information	
Record Type	Link AER** Number
No duplicate or linked report.	

**Adverse Reaction Term** 

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)	

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

### Canada Vigilance

Report Runtime: Initial Received Date: Latest Received Date: Total Number of Reports:

**Reaction Duration** 

2019-03-07 - 02:42:47 PM 1965-01-01 to 2018-11-30 N/A

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Summary of Reported Adverse Reactions
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**Adverse Reaction Term(s)** 

Death

Seizure

Encephalopathy

Report Informatio	n	**AE	R = Adverse Re	eaction Report								
Adverse Reaction Report Number		ER Version nber	Initial Receiv	eceived Date Latest Rece		eived Date	Source	of Report	Market Authorization Holder AER Numbe		Type of Report	Reporter Type
000057594		0	<mark>1986</mark> -11	-04	1986-1	1-04	0	ther			Spontaneous	
Serious re	eport?			Death	: Yes			Disabilit	y:		Congenital	Anomaly:
Yes			Li	fe Threatening	:		Ho	spitalizatio	n:	Other Med	dically Important Co	onditions:
Patient Information	n											
Age	Gender		Height	Weigh	t		Report C	Outcome				
16 Months	Female				Death							
Link / Duplicate R	eport Info	rmation										
	Recor	d Type			Link AER** Number							
No duplicate or link	ced report.											
<b>Product Informati</b>	on											
Product Description Health Product Role		Dosage For	m	Route Administr		Dose	Fr	equency	Therapy Duration	Indication(s)		
MMR II Suspect		LIQUID SUBCUTANEO	DUS									
Adverse Reaction Information	Term											

**MedDRA Version** 

v.21.1

v.21.1 v.21.1

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Report Runtime: Initial Received Date: Latest Received Date: Total Number of Reports:

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9 Report(s)

Report Information

\*\*AER = Adverse Reaction Report

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Market Authorization Holder AER Number	Type of Report	Reporter Type
000091883	0	1966-03-03	1966-03-03		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
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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Summary of Reported Adverse Reactions

Report Informat	ion	**AE	R = Adverse R	Reaction Re	port								
Adverse Reaction Report		ER Version mber	rsion Initial Received Date Latest Recei				ived Date	Sourc	e of Report	Autho	arket orization ER Number	Type of Report	Reporter Type
000097310		0	<mark>1967-</mark> 1	1-17	19	967-1	1-17	Н	lospital			Spontaneous	
Serious	report?				Death:	Yes			Disabilit	y:		Congenital	Anomaly:
Ye	es		L	ife Threate	ening:			Н	ospitalizatio	n:	Other Med	dically Important Co	onditions:
Patient Informat	ion												
Age	Gender		Height	V	/eight			Report	Outcome				
11 Months	Male						Death						
Link / Duplicate	Report Info	rmation											
	Reco	rd Type					Link AER*	* Numb	er				
No duplicate or li	nked report.												
Product Informa	ntion												
Product Des	cription	Health Pro	oduct Role	Dosage	e Form		Route Administr		Dose	Fre	equency	Therapy Duration	Indication(s)
MEASLES VACO	CINE 📮	Sus	Suspect POWDER FOR SOLUTION SUBCUTANEOUS				Intramuso	cular					
Adverse Reaction	on Term												
	Adverse Reaction Term(s)						MedDRA Version Reaction Duration						

v.21.1

v.21.1

Pyrexia

Rash maculo-papular

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Summary of Reported Adverse Reactions

Report Informatio	n	**AE	R = Adverse I	Reaction Re	port							
Adverse Reaction Report Number		R Version	n Initial Received Date Latest Received			eived Date	ved Date   Source of Report   Auth			larket orization AER Number	Type of Report	Reporter Type
000115178		0	<mark>1972</mark> -12-27 1972-1			12-27	Co	mmunity			Spontaneous	
Serious re	port?			[	Death: Yes			Disabilit	y:		Congenital	Anomaly:
Yes				Life Threate	ening:		Н	ospitalizatio	n:	Other Med	dically Important Co	onditions:
Patient Informatio	n											
Age	Gender		Height	V	Veight		Report	Outcome				
5 Years	Male						D	eath				
Link / Duplicate R	eport Infor	rmation										
	Recor	d Type				Link AER*	* Numb	er				
No duplicate or link	ed report.											
Product Information	on											
Product Descr	ription	Health Pr	oduct Role	Dosag	e Form	Route Administr			Fr	equency	Therapy Duration	Indication(s)
ALLERGY INJECT	ION	Conc	omitant	NOT SP	ECIFIED							
M-R-VAX		Sus	spect		UID ANEOUS							
Adverse Reaction Information	Term											
Adverse Reaction Term(s)					Me	edDRA	Version		ı	Reaction Duration		
Conjunctivitis							v.21	.1				
Cyanosis	-						v.21	.1				
Pyrexia							v.21					
Stupor						v.21.1						

Vomiting

v.21.1 v.21.1

### Canada Vigilanaa

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Canada vigilance					
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Report Informati	on	**AE	R = Adverse F	Reaction Re	eport							
Adverse Reaction Report Number	Latest AER Version Number		Initial Recei	ved Date	Latest Rece	eived Date			Market Authorization Holder AER Number		Type of Report	Reporter Type
000647275		0	<b>2015</b> -03-19		2015-03-19		Cor	mmunity	2014ADR039		Spontaneous	Physician
Serious report?				Death: Yes			Disability:		y:	Congenital Anomaly:		
Ye	S		L	Life Threatening:			Hospitalization:			Other Medically Important Conditions:		
Patient Informati	on											
Age	Gender		Height	V	Veight		Report Outcome					
1 Years	1 Years Female			10 k	Kilograms Death							
Link / Duplicate	Report Info	rmation										
	Reco	rd Type				Link AER*	* Numb	er				
No duplicate or lin	ked report.											
Product Information	tion											
Product Desc	cription	Health Pro	oduct Role	Dosag	e Form	Route Administr		Dose	Fre	equency	Therapy Duration	Indication(s)
INFLUENZA VAC	IFLUENZA VACCINE —		spect	NOT SP	ECIFIED	Unknov	vn		Once			Immunisation
MMR S		Sus	spect		UID ANEOUS	Unknown		Once		Immunisation		
Adverse Reactio Information	n Term											
	Adverse Reaction Term(s)				Me	dDRA '	Version			Reaction Duration		

v.21.1

Death

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9 Report(s)

**Report Information** 

\*\*AER = Adverse Reaction Report

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date		Market Authorization Holder AER Number	Type of Report	Reporter Type
E2B_00515150	0	<mark>2015</mark> -10-16	2015-10-16	МАН	1510CAN007141	Spontaneous	Consumer Or Other Non Health Professional

Serious report?	Death:	Yes	Disability:	No	Congenital Anomaly:	No
Yes	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	