

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 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

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 Vigilanaa

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237 Report(s)

Canada vigilance	
Summary of Reported Adverse Reactions	•

Report Information	n	**AE	R = Adverse R	eaction Re	port							
Adverse Reaction Report Number	Latest AE Num		Initial Receiv	ed Date	Latest Rece			Market Authorization Holder AER Number		Type of Report	Reporter Type	
000000584	()	1973-08	1973-0	8-02	Н	lospital			Spontaneous		
Serious re	eport?			Į.	Death:		Disability: Conge					Anomaly:
Yes			L	ife Threat	ening:		Н	ospitalizatio	n: Yes	Other Med	dically Important Co	onditions:
Patient Information	on .											
Age	Gender		Height	V	Veight		Report	Outcome				
1 Years	Male						Recover	ed/resolved				
Link / Duplicate R	eport Infor	mation										
	Record	l Type				Link AER*	* Numb	er				
No duplicate or link	ked report.											
Product Informati	on											
Product Descr	ription	Health Pr	oduct Role	Dosag	e Form	Route Administr		Dose	Fre	equency	Therapy Duration	Indication(s)
ATTENUVAX	=	Sus	spect	NOT SP	ECIFIED	Parente	ral	0.5 mL				
Adverse Reaction Information	Term					_						
Adverse Reaction Term(s)					MedDRA Version				Reaction Duration			
Pyrexia Pyrexia						v.21	.1					

v.21.1

Seizure

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Summary of Reported Adverse Reactions

Report Information	n	**AE	R = Adverse R	Reaction Re	eport							
Adverse Reaction Report Number		R Version nber	Initial Recei	ved Date	Latest Rece	eived Date Source of Report Authorization Holder AER Numl		rization	Type of Report	Reporter Type		
000000585		0	<mark>1973</mark> -08	3-02	1973-0	8-02	H	ospital			Spontaneous	
Serious re			L	ife Threat	Death: ening:		Н	Disabilit ospitalizatio		Other Med	Congenital Anomaly: dically Important Conditions:	
Patient Information	on											
Age	Gender		Height	V	Weight Report Outcome							
2 Years	Male					Recovered/resolved						
Link / Duplicate R	eport Info	rmation										
	Recor	d Type				Link AER*	* Numbe	er				
No duplicate or link	ked report.											
Product Informati	ion											
Product Desc	ription	Health Pr	oduct Role	Dosag	je Form	Route Administr		Dose	Fre	equency	Therapy Duration	Indication(s)
ATTENUVAX		Sus	spect	NOT SP	PECIFIED	Parente	ral	0.5 mL				
Adverse Reaction Information	Term											
Adverse Reaction Term(s)					Me	dDRA \	/ersion			Reaction Duration		

v.21.1 v.21.1

Pyrexia

Seizure

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

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Summary of Reported	Adverse Reactions
 	·

NOT SPECIFIED

NOT SPECIFIED

Suspect

Suspect

Report Informatio	n	**AE	R = Adverse R	Reaction Re	port							
Adverse Reaction Report Number	Latest AEI Num		Initial Recei	ved Date	Latest Rece	ceived Date Source of Report Autho		Market Authorization Holder AER Number		Type of Report	Reporter Type	
000002147	0)	1974-02	2-15	1974-0	1974-02-15 Community				Spontaneous		
Serious re	port?			I	Death: Disabili			Disabilit	y:	Congenital Anomaly:		
Yes			L	ife Threat	tening: Hospitalization:			Other Me	dically Important Co	onditions:		
Patient Information	n									_		
Age	Gender		Height	V	Veight		Report	Outcome				
11 Months	Male						Unl	known				
Link / Duplicate R	eport Infori	mation								_		
	Record	І Туре				Link AER*	* Numb	er				
No duplicate or link	ed report.											
Product Informati	on											
Product Descr	iption	Health Pr	oduct Role	Dosag	e Form	Route Administr		Dose	Fi	requency	Therapy Duration	Indication(s)

Adverse Reaction Term
Information

ATTENUVAX

QUAD VACCINE

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	

Parenteral

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

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Adverse Reaction Report Number	Latest AER \		Initial Recei	ved Date	Latest Rece	ived Date	Source of	Report	Auth	larket orization AER Number	Type of Report	Reporter Type
000002399	0		1974-0	3-14	1974-0	3-14	MA	Н			Spontaneous	
Serious re	eport?				Death:			Disabilit	y:		Congenital	Anomaly:
Yes			L	ife Threat	ening:		Hosp	italizatio	n: Yes	Other Med	dically Important Co	onditions:
Patient Information	on											
Age	Gender		Height	V	Neight		Report Ou	tcome				
12 Months	Female						Death	1 =				
Link / Duplicate R	Report Informa	ation										
•	Record T	уре				Link AER*	* Number					
No duplicate or link	ked report.											
Product Informati	ion											
Product Descr	rintian III	aalth Dr	oduct Role	Deces	ie Form	Route	of	Dose		edilency	Therapy Duration	Indication(s)

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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Canada Vigilance
Summary of Reported Adverse Reactions

Report Informatio	n	**AE	**AER = Adverse Reaction Report									
Adverse Reaction Report Number		R Version nber	Initial Receive	ed Date	Latest Rece			Market Authorization Holder AER Number		Type of Report	Reporter Type	
000002637	(0	1974-03-	28	1974-0	3-28	Co	mmunity			Spontaneous	
Serious re	eport?			ı	Death:			Disabilit	:y:		Congenital	Anomaly:
Yes			Life	e Threate	ening:		H	ospitalizatio	n: Yes	Other Med	dically Important Co	onditions:
Patient Information	n											
Age	Gender		Height	V	Veight		Report	Outcome				
21 Months	Female					F	Recover	ed/resolved				
Link / Duplicate R	eport Infor	mation										
	Record	d Type			Link AER** Number							
No duplicate or link	ked report.											
Product Informati	on											
Product Descr	ription	Health Pro	oduct Role	Dosag	e Form	Route Administr		Dose	Fr	equency	Therapy Duration	Indication(s)
ATTENUVAX		Sus	pect	NOT SP	ECIFIED	Parente	ral				6.0 Day(s)	
Adverse Reaction Information	Term											
Adverse Reaction Term(s)						Me	dDRA	Version			Reaction Duration	
Ataxia 📁							v.21	.1				
Balance disorder						v.21.1						
Encephalitis =					v.21.1							
Pyrexia							v.21	.1				

v.21.1

Rash maculo-papular

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237 Report(s)

Canada Vigilance
Summary of Reported Adverse Reactions

Report Information	n
Adverse Reaction Report Number	La
000002876	
Serious re	ро
Yes	
Patient Informatio	n
Age	(
39 Months	ı
Link / Duplicate Ro	еp
No duplicate or link	ed
Product Information	on
Product Descr	int

**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
000002876	0	<mark>1974</mark> -04-26	1974-04-26	Community		Spontaneous	

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

1			
Gender	Height	Weight	Report Outcome
Female			Unknown

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

tion

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	



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

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237 Report(s)

Report Information	on	**AE	R = Adverse F	Reaction Re	eport							
Adverse Reaction Report Number		R Version	Initial Rece	ived Date	Latest Rece	eived Date	Date Source of Report Author		Market Authorization Holder AER Number		Type of Report	Reporter Type
000006133	(0	1975-0	3-24	1975-0)3-24	H	Hospital			Spontaneous	
Serious r	eport?				Death:			Disabilit	y:	Congenital Anomaly:		
Yes	S		l	_ife Threat	ening:		Н	ospitalizatio	n:	Other Me	dically Important Co	onditions:
Patient Information	on											
Age	Gender		Height	1	Weight		Report	Outcome				
17 Months				9 k	Kilograms		Unknown					
Link / Duplicate F	Report Infor	rmation										
	Record	d Type				Link AER*	* Numb	er				
No duplicate or lin	ked report.											
Product Informat	ion											
Product Desc	ription	Health Pro	oduct Role	Dosag	ge Form	Route Administr		Dose	Fr	equency	Therapy Duration	Indication(s)
M-R-VAX		Sus	spect		QUID FANEOUS	Subcutan	eous			every 1 Day(s)		
Adverse Reaction Information	n Term											
	Adv	erse Reac	tion Term(s)			MedDRA Version					Reaction Duration	
Pyrexia =							v.21	.1				

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237 Report(s)

Report Informatio	n	**AE	**AER = Adverse Reaction Report									
Adverse Reaction Report Number		ER Version mber	Initial Recei	ved Date	e Latest Received Date Source of Report Auth				larket orization AER Number	Type of Report	Reporter Type	
000007752		0	1975-1	0-07	1975-1	10-07		Other			Spontaneous	
Serious re	eport?			ı	Death:			Disabilit	y:		Congenital	Anomaly:
Yes			L	ife Threat	ening:		Н	ospitalizatio	n:	Other Med	dically Important Co	onditions:
Patient Information	n											
Age	Gender		Height	V	Veight		Report	Outcome				
14 Months		76	Centimetres	13 k	Kilograms	Unknown						
Link / Duplicate R	eport Info	rmation										
	Recor	d Type				Link AER*	* Numb	er				
No duplicate or link	ed report.											
Product Informati	on											
Product Descr	ription	Health Pr	oduct Role	Dosag	e Form	Route Administr		Dose	Fr	requency	Therapy Duration	Indication(s)
MMR		Sus	spect		UID ANEOUS	Subcutan	eous	0.5 mL	1	every 1 Day(s)	1.0 Day(s)	
Adverse Reaction Information	Term											
Adverse Reaction Term(s)					Me	edDRA	Version			Reaction Duration		
Febrile convulsion	_ <mark> </mark>						v.21	.1				
Pyrexia							v.21	.1				

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Report Information	on	**AE	R = Adverse R	eaction Re	eport							
Adverse Reaction Report Number		ER Version mber	rsion Initial Received Date La		Latest Rece	eived Date Source		e of Report	Market Authorization Holder AER Number		Type of Report	Reporter Type
000009341		0	<mark>1976</mark> -03-17 1976-			3-17					Spontaneous	Physician
Serious report?				I	Death:			Disabilit	y:		Congenital	Anomaly:
Yes	Yes			ife Threat	ening:		Н	ospitalizatio	n:	Other Me	dically Important Co	onditions:
Patient Informati	on											
Age	Gender		Height	\	Neight		Report	Outcome				
13 Months				11	Kilograms		Unl	known				
Link / Duplicate F	Report Info	rmation										
	Recor	d Type				Link AER*	* Numb	er				
No duplicate or lin	ked report.											
Product Informat	tion											
Product Desc	ription	Health Pr	oduct Role	Dosag	ge Form	Route Administr		Dose	Fı	requency	Therapy Duration	Indication(s)
MMR		Sus	spect		QUID FANEOUS	Subcutan	eous	0.5 mL	1	every 1 Day(s)	1.0 Day(s)	
Adverse Reaction	n Term											
Adverse Reaction Term(s)					Me	MedDRA Version				Reaction Duration		
Febrile convulsion	1						v.21	.1				

v.21.1 v.21.1

Pyrexia

Rash erythematous

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Canada Vigilance
Summary of Reported Adverse Reactions

Report Information	on	**AE	R = Adverse Re	action Re	eport							
Adverse Reaction Report Number		R Version	Initial Received Date Latest Received		ived Date	Sourc	e of Report	Market Authorization Holder AER Number		Type of Report	Reporter Type	
000009860		0	1976-04	1976-04-23 1976-04							Spontaneous	Physician
Serious r			I	Death:			Disabilit	y:		Congenital	Anomaly:	
Yes			Lit	e Threat	ening:		Н	ospitalizatio	n:	Other Med	dically Important Co	onditions:
Patient Information	on											
Age	Gender		Height	V	Veight	Report Outcome						
15 Months	Female					Unknown						
Link / Duplicate F	Report Info	rmation										
	Recor	d Type				Link AER** Number						
No duplicate or lin	ked report.											
Product Informat	ion											
Product Desc	ription	Health Pr	oduct Role	Dosag	e Form	Route Administr		Dose	Fr	equency	Therapy Duration	Indication(s)
MMR	MR Suspect SU			UID ANEOUS	Subcutan	bcutaneous 1.0 Dosage forms			every 1 Day(s)	1.0 Day(s)		
Adverse Reaction Information	n Term					,						
Adverse Reaction Term(s)					MedDRA Version				Reaction Duration			
Pyrexia					v.21	.1						

v.21.1

v.21.1

Rash erythematous

Seizure

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

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Canada Vigilance
Summary of Reported Adverse Reactions

Report Information	on	**AE	R = Adverse F	Reaction Re	port									
Adverse Reaction Report Number		ER Version mber	Initial Recei	ved Date	ed Date Latest Received Date		Source	e of Report	Market Authorization Holder AER Number		Type of Report	Reporter Type		
000009867 0			1976-0	4-28	1976-0)4-28					Physician			
Serious r	Serious report?			[Death:	Disability: Congenital					Anomaly:			
Yes	8		L	ife Threat	ening:		Н	ospitalizatio	n:	Other Med	dically Important Co	onditions:		
Patient Informati	on													
Age	Gender		Height Weight				Report	Outcome						
3 Years Female							Unk	nown						
Link / Duplicate F	Report Info	rmation												
	Recor	d Type				Link AER*	* Numbe	er						
No duplicate or lin	ked report.													
Product Informat	ion													
Product Desc	ription	Health Pr	oduct Role	Dosag	e Form	Route Administr	-	Dose	Fre	equency	Therapy Duration	Indication(s)		
RUBELLA VACCI	NE	Sus	spect	NOT SP	PECIFIED	Subcutan	Subcutaneous 1.0 Dosage forms			every 1 Day(s)	1.0 Day(s)			
Adverse Reaction Information	n Term													
Adverse Reaction Term(s)					Me	MedDRA Version Reaction			Reaction Duration					
Angioedema = -							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		Market Authorization Holder AER Number	Type of Report	Reporter Type
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	se Frequency Therapy Duration I		
ATTENUVAX	UVAX Suspect NOT		Parenteral				

Adverse Reaction Term Information

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



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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Report Information	on	**AE	R = Adverse F	Reaction Re	eport								
Adverse Reaction Report Number		R Version	rsion Initial Received Da		Latest Received Date		Source	e of Report	Market Authorization Holder AER Number		Type of Report	Reporter Type	
000010963		0	1976 -09-09 1976-09			9-09					Spontaneous	Physician	
Serious report? Death:					Death:			Disabilit	y:	Congenital Anomaly:			
Yes	3		L	ife Threat	ening:		Н	ospitalizatio	n:	Other Me	dically Important Co	onditions:	
Patient Information													
Age	Gender		Height	1	Weight Report Outcome								
13 Months	Female					F	Recover	ed/resolved					
Link / Duplicate R	Report Info	rmation											
	Recor	d Type				Link AER*	* Numb	er					
No duplicate or line	ked report.												
Product Informat	ion												
Product Desc	ription	Health Pro	oduct Role	Dosag	ge Form	Route Administr		Dose	Fr	equency	Therapy Duration	Indication(s)	
MMR	MMR Suspect SU				QUID TANEOUS	Subcutan	eous			every 1 Day(s)			
Adverse Reaction Information	n Term					_							
	Adverse Reaction Term(s)					Me	MedDRA Version				Reaction Duration		
Decreased appetit	e						v.21.1						

v.21.1

v.21.1 v.21.1

v.21.1

Encephalitis

Rash maculo-papular

Pyrexia

Vomiting

2019-03-07_exportPDF.pdf

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	Market Authorization Holder AER Number	Type of Report	Reporter Type
000012147	0	<mark>1977</mark> -01-26	1977-01-26		Spontaneous	Consumer Or Other Non Health Professional

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

ranem miorination	ent Information	on
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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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Canada Vigilance
Summary of Reported Adverse Reactions

Report Information **AER = Adverse Reaction Report												
Adverse Reaction Report Number		ER Version mber	I INITIAL ROCOLVON LIATO I LATOST ROCOLV			ived Date	ate Source of Report Auth			larket orization AER Number	Type of Report	Reporter Type
000012148		0	<mark>1977</mark> -01-26 1977-0					MAH			Spontaneous	
Serious re				Death:			Disabilit	y:	Congenital Anomaly:			
Yes			L	ife Threat	ening:		Н	ospitalizatio	n: Yes	Other Med	dically Important Co	
Patient Information												
Age	Gender		Height	l v	Veight		Report	Outcome				
14 Months Male						Not recovered/not resolved						
Link / Duplicate R	eport Info	rmation										
	Recor	d Type				Link AER*	* Numb	er				
No duplicate or link	ked report.											
Product Informati	on											
Product Descr	ription	Health Pr	oduct Role	Dosag	je Form	Route Administr		Dose	Fr	equency	Therapy Duration	Indication(s)
MMR		Sus	spect		QUID FANEOUS			0.5 mL				
Adverse Reaction Information	Term											
	Ad	verse Reac	tion Term(s)			MedDRA Version				Reaction Duration		
Encephalitis							v.21					
Hemiplegia =						v.21.1						

v.21.1

v.21.1

Respiratory failure

Seizure

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Canada Vigilance
Summary of Reported Adverse Reactions

Report Information	eport Information **AER = Adverse Reaction Report											
Adverse Reaction Report Number		Initial Recei	ved Date	Date Latest Received Date		Sourc	e of Report	Market Authorization Holder AER Number		Type of Report	Reporter Type	
000014062		0 1977-07-12 197				7-12		Other			Spontaneous	
Serious re Yes	L	ife Threat	Death: ening:		Н	Disabilit ospitalizatio		Other Med	Congenital			
Patient Information												
Age	Gender		Height	Veight	Report Outcome							
1 Years Male						Recovered/resolved						
Link / Duplicate R	eport Info	rmation										
	Recor	d Type				Link AER*	* Numb	er				
No duplicate or link	ked report.											
Product Informati	on											,
Product Description Health Product		oduct Role	Dosag	e Form	Route Administr		Dose	Frequency		Therapy Duration	Indication(s)	
ATTENUVAX		Sus	spect	NOT SP	ECIFIED	Parenteral						
Adverse Reaction Information	Term											
	Adv	erse Reac	tion Term(s)			Me	dDRA	Version			Reaction Duration	

v.21.1

v.21.1

v.21.1

Encephalitis

Pyrexia

Febrile convulsion

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Canada Vigilance
Summary of Reported Adverse Reactions

Report Informatio	n	**AE	R = Adverse R	eaction Re	eport							
Adverse Reaction Report Number		R Version nber	Initial Receiv	ed Date	Latest Rece	eived Date	Sourc	e of Report	Market Authorization Holder AER Number		Type of Report	Reporter Type
000014066	()	1977-07	'-12	1977-0	7-12		Other			Spontaneous	
Serious re	eport?			ı	Death:			Disabilit	y:	Congenital Anomal		
Yes			Li	ife Threat	ening:		Н	ospitalizatio	n: Yes	Other Med	dically Important Co	onditions:
Patient Information	n											
Age					Veight		Report	Outcome				
13 Months	Male				_			ed/resolved				
Link / Duplicate R	eport Infor	mation										
	Record	d Type			Link AER** Number							
No duplicate or link	ked report.											
Product Informati	on											
Product Descr	ription	Health Pr	oduct Role	Dosag	je Form	Route Administr		Dose	Fre	equency	Therapy Duration	Indication(s)
ATTENUVAX Suspect NC		NOT SP	PECIFIED	Subcutan	eous							
Adverse Reaction Information	Term					_						
	Adv	erse Reac	tion Term(s)			Me	dDRA	Version			Reaction Duration	
Bronchitis							v.21	.1				

v.21.1

v.21.1

v.21.1

v.21.1

Conjunctivitis

Erythema

Pyrexia

Rhinitis

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

237 Report(s)

Summary of Reported Adverse R

**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
000014403	0	<mark>1977</mark> -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	tion			
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	
1 I Ouuct	milomiation	

Report 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	

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Canada Vigilance
Summary of Reported Adverse Reactions

Report Information	on	**AE	ER = Adverse F	Reaction Re	eport							
Adverse Reaction Report Number		ER Version nber	Initial Recei	ved Date	Latest Rece	eived Date	Sourc	e of Report	Auth	larket orization AER Number	Type of Report	Reporter Type
000015132		0	1977-1	0-31	1977-1	0-31				Spontaneous Physicia		
Serious r	eport?				Death:			Disability	y:		Congenital	Anomaly:
Yes	3		L	ife Threat	ening:		Н	ospitalizatio	n: Yes	Other Med	dically Important Co	onditions:
Patient Information	on											
Age	Gender		Height	1	Neight		Report	Outcome				
1 Years Female 79 Centimetres 12 Kilograms					F	Recovered/resolved						
Link / Duplicate F	Report Info	rmation										
	Recor	d Type				Link AER*	* Numb	er				
No duplicate or lin	ked report.											
Product Informat	ion											
Product Desc	ription	Health Pi	roduct Role	Dosag	ge Form	Route Administr		Dose	Fr	equency	Therapy Duration	Indication(s)
MMR		Su	spect		QUID FANEOUS	Subcutan	eous	1.0 Dosage forms	e 1	every 1 Day(s)		
Adverse Reaction Information	n Term											
	Ad	verse Read	ction Term(s)			Me	edDRA	Version			Reaction Duration	
Lethargy							v.21	.1				

v.21.1

v.21.1

v.21.1 v.21.1

Leukopenia

Rash maculo-papular

Pyrexia

Vomiting

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Reporter Type

Indication(s)

Adverse Reaction Report Number	Latest AER Numb		Initial Rece	ived Date	Latest Rece	test Received Date		e of Report	Auth	arket orization ER Number	Type of Report	Reporter T
000016806	0		1978-0	4-26	1978-0	04-26 MAH					Spontaneous	
Serious re	port?			[Death:			Disabilit	y:		Anomaly:	
Yes				ife Threate	ening:		Н	ospitalizatio	n:	Other Med	dically Important Co	onditions:
Patient Information	n											
Age Gender Height			V	Weight Report Outo			Outcome					
16 Months	Female	72	Centimetres	11 k	11 Kilograms Recovered/resolved							
Link / Duplicate R	eport Inform	ation										
	Record 1	Гуре				Link AER*	* Numb	er				
No duplicate or link	ed report.											
Product Informati	on											_
Product Descr	iption H	lealth Pr	oduct Role	Dosag	e Form	Route Administr		Dose	Fre	equency	Therapy Duration	Indication
MMR		Suspect SUB(UID ANEOUS					T		

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

Adverse Reaction Term

Adverse Reaction Term(s)

Information

Febrile convulsion

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

Reaction Duration

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Canada Vigilance
Summary of Reported Adverse Reactions

Report Information	n	**AE	R = Adverse R	Reaction Re	eport							
Adverse Reaction Report Number		R Version nber	Initial Recei	ved Date	Latest Rece	eived Date	Sourc	e of Report	Market Authorization Holder AER Number		Type of Report	Reporter Type
000018276	(0	1978-08	3-17	1978-0)8-17					Spontaneous	Physician
Serious re	eport?				Death:			Disabilit	y:		Congenital	Anomaly:
Yes			L	ife Threat	ening:		Н	ospitalizatio	n:	Other Med	dically Important Co	onditions:
Patient Information	on .											
Age	Gender		Height	V	Veight		Report	Outcome				
15 Months	Male	81	Centimetres	11	Kilograms	rams Unknown						
Link / Duplicate R	eport Infor	mation										
	Record	d Type			Link AER** Number							
No duplicate or link	ked report.											
Product Informati	on											
Product Desci	ription	Health Pr	oduct Role	Dosag	je Form	Route Administr		Dose	Fr	equency	Therapy Duration	Indication(s)
DIPHTHERIA AND TETANUS TOXOII PERTUSSIS VACO ADSORBED	OS WITH	Conc	omitant		QUID USCULAR	Subcutan	eous					
MMR		Sus	spect		QUID FANEOUS			1.0 Dosag forms		every 1 Day(s)	1.0 Day(s)	

MedDRA Version

v.21.1

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

237 Report(s)

Report Information	**AER = Adve

**AER = Adverse Reaction Report

Adver Reaction I Numb	Report	Latest AER Version Number Initial Received		Latest Received Date		Market Authorization Holder AER Number	Type of Report	Reporter Type
000018	766	0	<mark>1978</mark> -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

1 -								
	Product Description	duct Description Health Product Role Dosag		Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
A	TTENUVAX	Suspect	NOT SPECIFIED	Parenteral				

Adverse Reaction Term Information

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A 237 Report(s)

Canada Vigilance
Summary of Reported Adverse Reactions

Report Information	on	**AEI	R = Adverse R	eaction Re	eport							
Adverse Reaction Report Number	Latest AE Num		Initial Recei	ved Date	Latest Rece	ived Date	Sourc	e of Report	Market Authorization Holder AER Number		Type of Report	Reporter Type
000019989)	1979-02	2-19	1979-0	2-19	F	lospital			Spontaneous	
Serious r	eport?			l	Death:			Disabilit	y:		Congenital	Anomaly:
Yes	5		L	ife Threat	ening:		Н	ospitalizatio	n: Yes	Other Med	dically Important Co	onditions:
Patient Information	on											
Age	Gender		Height	V	Veight		Report	Outcome				
18 Months	Male					Unknown						
Link / Duplicate F	Report Infor	mation										
	Record	d Type				Link AER*	* Numb	er				
No duplicate or lin	ked report.											
Product Informat	ion											
Product Desc	ription	Health Pro	oduct Role	Dosag	e Form	Route Administr		Dose	Fre	equency	Therapy Duration	Indication(s)
MEASLES VACCI	NE	Sus	spect	SOLU	ER FOR JTION ANEOUS							
Adverse Reaction Information	n Term											
	Adverse Reaction Term(s)					Me	dDRA	Version			Reaction Duration	

v.21.1 v.21.1

v.21.1

Dehydration

Pharyngitis

Pyrexia

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Report Information	n	**AE	R = Adverse F	Reaction Re	eport								
Adverse Reaction Report Number		R Version nber	Initial Recei	ved Date	Latest Received Date Source of Report Authoriza Holder AER N		orization	Type of Report	Reporter Type				
000019993		0	1979-0	2-19	1979-0	2-19	F	lospital		Spontaneous			
Serious re	-		L		Death: Threatening:			Disabilit ospitalizatio		Other Med	Anomaly: onditions:		
Patient Informatio	n								·				
Age 1 Years	Gender Female		Height	V	Veight			Outcome known	me				
Link / Duplicate Ro	eport Info	rmation											
		d Type				Link AER** Number							
No duplicate or link	ed report.												
Product Information	on												
Product Descr	iption	Health Pr	oduct Role	Dosag	je Form	Route Administr		Dose	Fr	equency	Therapy Duration	Indication(s)	
MMR		Sus	spect		QUID FANEOUS								
Adverse Reaction Information	Term												
Adverse Reaction Term(s)						Me	edDRA	Version			Reaction Duration		
Pyrexia							v.21	.1					
Rash erythematous	3						v.21	.1					

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Canada Vigilance
Summary of Reported Adverse Reactions

Report Information	on	**AE	R = Adverse F	Reaction Re	eport									
Adverse Reaction Report Number		R Version nber	Initial Recei	ved Date	Latest Rece	ived Date	Sourc	e of Report	Autho	arket orization ER Number	Type of Report	Reporter Type		
000019994		0	1979-0	2-19	1979-0	2-19	Н	lospital			Spontaneous			
Serious r	eport?				Death: Disability:			y:	Congenital Anomaly:					
Yes	3		L	ife Threat	ening:		Н	ospitalizatio	n: Yes	Other Med	Other Medically Important Conditions:			
Patient Information	on													
Age	Gender		Height	V	Veight		Report	Outcome						
1 Years	Female						Unl	known						
Link / Duplicate F	Report Infor	rmation												
	Recor	d Type				Link AER*	* Numb							
No duplicate or lin	ked report.													
Product Informat	ion													
Product Desc	ription	Health Pr	oduct Role	Dosag	e Form	Route Administr		Dose	Fre	equency	Therapy Duration	Indication(s)		
RUBELLA VACCII	NE	Sus	spect	NOT SP	ECIFIED									
Adverse Reaction Information	n Term													
Adverse Reaction Term(s)						Me	dDRA	Version			Reaction Duration			

v.21.1

Febrile convulsion

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Report Information	n	**AE	R = Adverse F	Reaction Re	port									
Adverse Reaction Report Number		R Version nber	Initial Received Date Latest Received Date Source of Report Holder AER Number				rization	Type of Report	Reporter Type					
000021505	()	1979-0	5-16	1979-0	5-16	(Other			Spontaneous			
Serious re	eport?				Death:	Disability:		y:	Congenital Anoma					
Yes			L	ife Threate	ening:		H	ospitalizatio	n:	Other Med	dically Important Co	onditions:		
Patient Information														
Age	Gender		Height	V	Veight		Report	Outcome						
1 Years	Female					F	Recover	ed/resolved						
Link / Duplicate R	eport Infor	mation												
	Record	d Type				Link AER*	* Numb							
No duplicate or link	ked report.													
Product Informati	ion													
Product Desci	ription	Health Pro	oduct Role	Dosag	e Form	Route Administr		Dose	Fre	equency	Therapy Duration	Indication(s)		
ATTENUVAX		Sus	spect	NOT SP	ECIFIED	Parente	ral							
Adverse Reaction Information	Term													
	Adverse Reaction Term(s)					MedDRA Version					Reaction Duration			

v.21.1

v.21.1

Febrile convulsion

Rash erythematous

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Canada Vigilance
Summary of Reported Adverse Reactions

Report Information	on	**AE	R = Adverse I	Reaction R	eport									
Adverse Reaction Report Number		ER Version mber	Initial Rece	ived Date	Latest Rece	eived Date	Sourc	e of Report	Autl	Market norization AER Number	Type of Report	Reporter Type		
000021947		0	1979-0	9-18	1979-0	09-18		Other			Spontaneous			
Serious r	eport?				Death:			Disabilit	y:		Congenital Anomaly:			
Yes	S			Life Threat	ening:		Н	lospitalizatio	n: Yes	Other Me	dically Important Co	onditions:		
Patient Information	on													
Age	Gender		Height	1	Weight		Report	Outcome						
14 Months	Male			10	Kilograms	F	Recover	ed/resolved						
Link / Duplicate F	Report Info	rmation								_				
	Recor	d Type				Link AER*	* Numb	er						
No duplicate or lin	ked report.													
Product Informat	tion													
Product Desc	ription	Health Pr	oduct Role	Dosag	ge Form	Route Administr		Dose	F	requency	Therapy Duration	Indication(s)		
MMR		Sus	spect		QUID TANEOUS	Subcutan	eous			1.0 Day(s)				
Adverse Reaction Information	n Term													
	Adverse Reaction Term(s)					MedDRA Version					Reaction Duration			
Febrile convulsion)						v.21	l.1						

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Report Informatio	n	**AE	R = Adverse F	Reaction R	eport e									
Adverse Reaction Report Number		ER Version mber	Initial Received Date Latest R			eived Date Source of Report			Market Authorization Holder AER Number		Type of Report	Reporter Type		
000021950		0	1979-0	9-18	1979-0	9-18		Other			Spontaneous			
Serious re	port?				Death:			Disabilit	y:		Congenital	Anomaly:		
Yes			l	_ife Threa	tening:		Н	ospitalizatio	n: Yes	Other Med	dically Important Co	onditions:		
Patient Information	on .													
Age	Gender		Height		Weight		Report	Outcome						
17 Months	Female			12	Kilograms		Unknown							
Link / Duplicate R	eport Info	rmation												
	Recor	d Type				Link AER*	* Numb	er						
No duplicate or link	ed report.													
Product Informati	on				,									
Product Descr	ription	Health Pr	oduct Role	Dosa	ge Form	Route Administr		Dose	Fr	equency	Therapy Duration	Indication(s)		
MMR		Sus	spect	LI(SUBCU	QUID TANEOUS	Subcutan	eous							
Adverse Reaction Information	Term													
Adverse Reaction Term(s)						MedDRA Version					Reaction Duration			
Pyrexia							v.21							
Rash erythematous	S						v.21	.1						

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A 237 Report(s)

Canada Vigilance
Summary of Reported Adverse Reactions

Report Information	on	**AE	R = Adverse Re	action Re	port								
Adverse Reaction Report Number		R Version nber	Initial Receive	ed Date	Latest Rece	ived Date	Sourc	e of Report	Autho	arket orization ER Number	Type of Report	Reporter Type	
000023521	()	1980-02-	28	1980-0	2-28		Other		Spontaneous			
Serious r	eport?			[Death:			Disabilit	y:		Congenital	Anomaly:	
Yes	3		Lif	e Threate	ening:		Н	ospitalizatio	n: Yes	Other Med	dically Important Co	onditions:	
Patient Informati	on												
Age	Gender		Height	V	Veight		Report	Outcome					
7 Years	Male						Unl	known					
Link / Duplicate F	Report Infor	mation											
	Record	d Type				Link AER*	* Numb	er					
No duplicate or lin	ked report.												
Product Informat	ion												
Product Desc	ription	Health Pro	oduct Role	Dosag	e Form	Route Administr		Dose	Fre	equency	Therapy Duration	Indication(s)	
ATTENUVAX		Sus	spect	NOT SP	ECIFIED	Subcutan	eous	0.5 mL					
Adverse Reaction Information	n Term					_							
Adverse Reaction Term(s)						MedDRA Version					Reaction Duration		
Oedema =							v.21	.1					

Urticaria

v.21.1

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Report Informatio	n	**AE	R = Adverse R	eaction Re	eport								
Adverse Reaction Report Number		R Version	Initial Receiv	red Date	Latest Rece	ived Date	Sourc	e of Report	Auth	arket orization ER Number	Type of Report	Reporter Type	
000024450		0	1980-04	-09	1980-0	4-09		Other			Spontaneous		
Serious re	port?				Death:			Disabilit	y:	Congenital Anomaly:			
Yes			L	fe Threat	ening:		Н	ospitalizatio	n: Yes	Other Med	dically Important Co	onditions:	
Patient Informatio	n												
Age	Gender		Height	ight Weight Report Outcome									
1 Years	Female						Unl	known					
Link / Duplicate R	eport Info	rmation											
		d Type				Link AER*	* Numb	er					
No duplicate or link	ed report.												
Product Information	on												
Product Descr	ription	Health Pr	oduct Role	Dosag	ge Form	Route Administr		Dose	Fre	equency	Therapy Duration	Indication(s)	
MMR		Sus	spect		QUID FANEOUS								
Adverse Reaction Information	Term												
	Adverse Reaction Term(s)					MedDRA Version				Reaction Duration			

Febrile convulsion

v.21.1

Canada Vigilance ıs

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A 237 Report(s)

Summary of Reported Adverse Reactions

Report Informatio	n	**AE	R = Adverse I	Reaction Re	eport								
Adverse Reaction Report Number		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	
000024601		0	1980-0	06-11	1980-0	6-11		Other			Spontaneous		
Serious re	eport?				Death:			Disabilit	y:	Congenital Anomaly:			
Yes				Life Threat	ening:		Н	lospitalizatio	n: Yes	Other Med	dically Important Co	onditions:	
Patient Information	n												
Age	Gender		Height	ı	Weight		Report	Outcome					
3 Years	Male					F	Recover	ed/resolved					
Link / Duplicate R	eport Info	rmation											
	Recor	d Type				Link AER*	* Numb	er					
No duplicate or link	ced report.												
Product Informati	on												
Product Descr	ription	Health Pr	oduct Role	Dosag	ge Form	Route Administr		Dose	F	requency	Therapy Duration	Indication(s)	
MMR		Sus	spect		QUID TANEOUS	Subcutan	eous						
Adverse Reaction Information	Term					_							
Adverse Reaction Term(s)						MedDRA Version					Reaction Duration		
Bronchospasm						v.21.1							
Pyrexia	-						v.21	l.1					

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Report	Information
ινοροιτ	IIIIOIIIIatioii

**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
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	

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Report Information	on	**AE	R = Adverse F	Reaction R	eport							
Adverse Reaction Report Number		ER Version mber			ate Latest Received Date		Sourc	e of Report	Market Authorization Holder AER Number		Type of Report	Reporter Type
000024673		0	1980-02-18 1980-0)2-18		Other			Spontaneous	
Serious r	eport?				Death:			Disability	/ :		Congenital	Anomaly:
Yes	5			_ife Threa	tening:		Н	lospitalization	n:	Other Med	dically Important Co	onditions:
Patient Informati	on											
Age	Gender		Height		Weight		Report	Outcome				
13 Months	Male					Not	recover	ed/not resolve	d			
Link / Duplicate F	Report Info	rmation										
	Recor	d Type				Link AER*	* Numb	er				
No duplicate or lin	ked report.											
Product Informat	ion											
Product Desc	ription	Health Pr	oduct Role	Dosa	ge Form	Route Administr		Dose	Fr	equency	Therapy Duration	Indication(s)
MEASLES VACCINE Suspe		spect	POWDER FOR SOLUTION SUBCUTANEOUS									
TEGRETOL 📁		Drug used to treat AE NOT S		NOT S	PECIFIED	Oral 100.0 Milligra		am 3	every 1 Day(s)			
Adverse Reaction Information	n Term											
Adverse Reaction Term(s)						Me	dDRA	Version			Reaction Duration	

v.21.1

Electroencephalogram abnormal

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Canada Vigilance
Summary of Reported Adverse Reactions

Report Informati	on	**AE	R = Adverse R	Reaction Re	eport							
Adverse Reaction Repor Number	•	R Version	Initial Received Date Latest						Auth	larket orization AER Number	Type of Report	Reporter Type
000026308		0	1980-1	1-21	1980-1	1-21		Other			Spontaneous	
Serious	report?				Death:			Disabilit	y:		Congenital	Anomaly:
Ye	-		L	ife Threat	ening:		Н	ospitalizatio		Other Med	dically Important Co	
Patient Informat	ion											
Age	Gender		Height	١	Weight		Report	Outcome				
15 Months	Female					Unknown						
Link / Duplicate	Report Info	rmation										
	Recor	d Type				Link AER*	* Numb	er				
No duplicate or lin	nked report.											
Product Informa	tion											
Product Des	cription	Health Pro	oduct Role	Dosag	ge Form	Route Administr		Dose	Fr	equency	Therapy Duration	Indication(s)
MERUVAX 📮		Sus	spect	POWDER FOR SOLUTION SUBCUTANEOUS								
Adverse Reaction	n Term											
	Adv	erse Reac	tion Term(s)			Me	dDRA	Version			Reaction Duration	
Thrombocytopeni	a 📜						v.21	.1				

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Canada Vigilance
Summary of Reported Adverse Reactions

Report Informatio	n	**AEI	R = Adverse R	eaction Re	eport							
Adverse Reaction Report Number		ER Version mber	Initial Received Hate I Latest Received			eived Date	Sourc	e of Report	Auth	arket orization LER Number	Type of Report	Reporter Type
000026733		0	1981-01	-22	1981-0)1-22		Other			Spontaneous	
Serious re	port?				Death:			Disabilit	y:		Congenital	Anomaly:
Yes			L	ife Threat	ening:		Н	ospitalizatio	n: Yes	Other Med	dically Important Co	onditions:
Patient Informatio	n											
Age	Gender		Height	V	Veight		Report	Outcome				
12 Months	Female					Not	recover	ed/not resolve	ed			
Link / Duplicate R	eport Info	rmation										
		d Type				Link AER*	* Numb	er				
No duplicate or link	ed report.											
Product Information	on											
Product Descr	iption	Health Pro	oduct Role	Dosag	e Form	Route Administr	<u> </u>	Dose	Fr	equency	Therapy Duration	Indication(s)
MMR		Sus	spect		UID ANEOUS	Subcutan	eous	0.5 mL				
Adverse Reaction Information	Term											
Adverse Reaction Term(s)					Me	edDRA	Version			Reaction Duration		
Encephalitis							v.21	.1				
Melaena =							v.21	.1				

v.21.1

v.21.1

Paralysis

Vomiting

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Report Information	n	**AEI	R = Adverse R	Reaction Re	eport							
Adverse Reaction Report Number	Latest AEF		rsion Initial Received Date Latest Received Date Source of Report Authorize		Market norization AER Number	Type of Report	Reporter Type					
000028070	0)	1981-05	5-04	1981-0	5-04	Н	ospital			Spontaneous	
Serious re	port?				Death:			Disabilit	y:		Congenital	Anomaly:
Yes			L	ife Threat	ening:		H	ospitalizatio	n: Yes	Other Me	dically Important Co	onditions:
Patient Information	on											
Age	Gender		Height	V	Weight Report Outcome							
13 Months	Male					F	Recover	ed/resolved				
Link / Duplicate R	eport Infori	mation										
	Record	I Туре		Link AER** Number								
No duplicate or link	ed report.											
Product Informati	on											
Product Descr	Product Description Health Product Role				je Form	Route Administr		Dose	F	requency	Therapy Duration	Indication(s)
MMR		Sus	spect		LIOUID		eous			1 every 1 Day(s)	1.0 Day(s)	

Adverse Reaction T	erm
Information	

Drug used to treat AE

TEMPRA

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

NOT SPECIFIED

Oral

Canada Vigilanco

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

Reaction Duration

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Canada vigilance
Summary of Reported Adverse Reactions

Report Informatio	n	**AE	R = Adverse F	Reaction Re	eport								
Adverse Reaction Report Number	Latest AE Num	R Version nber			Latest Received Date		Sourc	e of Report	Auth	larket orization AER Number	Type of Report	Reporter Type	
000028312	()	1981-0	5-25	1981-0	5-25		Other			Spontaneous		
Serious re	Serious report?				Death:			Disabilit	y:	Congenital Anomaly:			
Yes	Yes				ening:		Н	ospitalizatio	n: Yes	Other Med	dically Important Co	onditions:	
Patient Information	n												
Age	Gender		Height	V	Weight Report Outcome								
23 Months	Female				Recovered/resolved								
Link / Duplicate R	eport Infor	mation											
•	Record				Link AER** Number								
No duplicate or link	ed report.												
Product Informati	on												
Product Descr	Product Description Health Product Role				je Form	Route Administr		Dose	Fr	equency	Therapy Duration	Indication(s)	
ATTENUVAX		Sus	Suspect NOT		ECIFIED								
Adverse Reaction Information	Term					,							

MedDRA Version

v.21.1

Adverse Reaction Term(s)

Febrile convulsion

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

Report Information	on	**AE	R = Adverse R	eaction Re	eport							
Adverse Reaction Report Number		ER Version mber	Initial Recei	ved Date	Latest Rece	eived Date	Sourc	e of Report	Market Authorization Holder AER Number		Type of Report	Reporter Type
000029035	000029035 0 1981-08-26 19					8-26		Other			Spontaneous	
Serious report?				ı	Death:			Disabilit	y:		Congenital	Anomaly:
Yes			L	ife Threat	ening:		Н	ospitalizatio	n:	Other Med	dically Important Co	onditions:
Patient Information	on											
Age	Gender		Height	V	Veight		Report	Outcome				
18 Months	Female					Unknown						
Link / Duplicate F	Report Info	rmation										
	Reco	d Type				Link AER*	* Numb	er				
No duplicate or lin	ked report.											
Product Informat	ion											_
Product Desc	ription	Health Pr	oduct Role	Dosag	je Form	Route Administr		Dose	Fı	equency	Therapy Duration	Indication(s)
MMR		Sus	spect		QUID FANEOUS	Subcutan	eous 0.5 mL					
Adverse Reaction Term Information						_						
		Me	edDRA	Version			Reaction Duration					
Cough		v.21.1										
Febrile convulsion							v.21	.1				

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

Canada Vigilance
Summary of Reported Adverse Reactions

Report Information	on	**AE	R = Adverse R	Reaction Re	eport							
Adverse Reaction Report Number		ER Version nber				eived Date				arket orization ER Number	Type of Report	Reporter Type
000029036	000029036 0 1981-08-26 1981-							Other			Spontaneous	
Serious r	Serious report? Death:							Disabilit	y:		Congenital	Anomaly:
Yes	3		L	ife Threat	ening:		Н	ospitalizatio	n: Yes	Other Med	dically Important Co	onditions:
Patient Information	on											
Age	Gender		Height	V	Veight		Report	Outcome				
15 Months	Male					Unknown						
Link / Duplicate F	Report Info	rmation										
	Recor	d Type				Link AER*	* Numb	er				
No duplicate or lin	ked report.											
Product Informat	ion											
Product Desc	ription	Health Pr	oduct Role	Dosag	je Form	Route Administr		Dose	Fre	equency	Therapy Duration	Indication(s)
MMR Suspect LIQUID SUBCUTANEOUS						Subcutan	eous	0.5 mL				
Adverse Reaction Term Information												
	Adv	verse Reac	tion Term(s)			Me	edDRA	Version			Reaction Duration	
Pyrexia							v.21	.1				

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

Report Informati	on	**AE	R = Adverse R	eaction Re	eport							
Adverse Reaction Repor Number		ER Version mber	Initial Received Date Latest Re			eived Date Source of Report			Market Authorization Holder AER Number		Type of Report	Reporter Type
000029083		0 1981-08-24			1981-0	08-24		Other			Spontaneous	
Serious	report?			ı	Death:			Disabilit	y:		Congenital	Anomaly:
Ye	S		L	ife Threat	ening:		Н	ospitalizatio	n:	Other Med	dically Important Co	onditions:
Patient Informat	ion											
Age	Gender		Height	\	Neight		Report	Outcome				
14 Months	Female						Un	known				
Link / Duplicate	Report Info	rmation										
	Recor	d Type		Link AER** Number								
No duplicate or lin	nked report.											
Product Informa	tion									,		
Product Desc	cription	Health Pr	oduct Role	Dosag	je Form	Route Administr		Dose	Fre	quency	Therapy Duration	Indication(s)
MMR II	MMR II Suspect											
Adverse Reaction	Adverse Reaction Term Information											
	Ad	verse Reac	tion Term(s)			Me	edDRA	Version			Reaction Duration	
Febrile convulsion	า					v.21.1						

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

Report Information	n	**AE	R = Adverse R	eaction Re	eport							
Adverse Reaction Report Number	Latest AEI Num		Initial Recei	ved Date	Latest Rece	ived Date	Sourc	e of Report	Auth	larket orization AER Number	Type of Report	Reporter Type
000029911	C)	<mark>1981</mark> -10)-16	1981-1	0-16		Other			Spontaneous	
Serious re	eport?				Death:			Disabilit	y:		Congenital	Anomaly:
Yes			L	ife Threat	ening:		Н	ospitalizatio	n: Yes	Other Med	dically Important Co	onditions:
Patient Information	on											
Age	Gender		Height	V	Neight		Report	Outcome				
2 Years	Female						Unl	known				
Link / Duplicate R	eport Infor	mation										
	Record	d Type				Link AER*	* Numb	er				
No duplicate or link	ked report.											
Product Informati	ion											
Product Desci	ription	Health Pr	oduct Role	Dosag	je Form	Route Administr		Dose	Fr	equency	Therapy Duration	Indication(s)
ATTENUVAX		Sus	spect	NOT SP	PECIFIED							
Adverse Reaction Term Information												
	Adverse Reaction Term(s)						MedDRA Version				Reaction Duration	
Febrile convulsion							v.21	.1				

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Canada Vigilance
Summary of Reported Adverse Reactions

Report Information	on	**AE	R = Adverse R	eaction Re	eport							
Adverse Reaction Report Number		R Version	Initial Received Date Latest Received				Sourc	e of Report	Auth	arket orization AER Number	Type of Report	Reporter Type
000030242		0	1981-06	1981-0	6-01		Other		Spontaneous			
Serious r	eport?				Death: Yes			Disabilit	y:		Congenital	Anomaly:
Yes	3		L	ife Threat	tening:		Н	ospitalizatio	n:	Other Med	dically Important Co	onditions:
Patient Information	on											
Age	Gender		Height	1	Weight		Report	Outcome				
2 Years	Female						D	eath				
Link / Duplicate R	Report Info	rmation										
	Recor	d Type			Link AER** Number							
No duplicate or lin	ked report.											
Product Informat	ion											
Product Desc	ription	Health Pr	oduct Role	Dosag	ge Form	Route Administr		Dose	Fr	equency	Therapy Duration	Indication(s)
MMR II	MMR II Suspect LIQUII SUBCUTAN										1.0 Day(s)	
Adverse Reaction Information												
	Adverse Reaction Term(s)							Version			Reaction Duration	
Coma							v.21	.1				

v.21.1

Vomiting

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

Report Information **AER = Adverse Reaction													
Adverse Reaction Report Number		R Version nber			te Latest Received Date		Source	of Report	Auth	arket orization ER Number	Type of Report	Reporter Type	
000030302		0	<mark>1981-</mark> 11	-17	1981-1	11-17	Ot	ther			Spontaneous		
Serious report?					Death:			Disability:			Congenital Anomaly:		
Yes			Li	ife Threat	ening:		Hos	spitalizatio	n: Yes	Other Med	dically Important Co	onditions:	
Patient Information	n												
Age	Gender		Height	V	Weight Report Outcome								
18 Months	Male		•		Unk								
Link / Duplicate R	eport Infor	mation											
•		d Type			Link AER** Number								
No duplicate or link	ed report.												
Product Informati	on												
Product Description Health Prod		oduct Role	Dosag	Dosage Form		of ation	Dose	Fr	equency	Therapy Duration	Indication(s)		
MMR Suspect SU			UID ANEOUS										
Adverse Reaction	Term												

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	

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

Canada Vigilance
Summary of Reported Adverse Reactions

Report Informati	on	**AE	R = Adverse F	Reaction Re	eport							
Adverse Reaction Repor Number		ER Version mber	I INITIAL ROCOLVON LIATO I LATOST ROCOLVO			eived Date	Sourc	e of Report	Auth	flarket norization AER Number	Type of Report	Reporter Type
000030571		0	<mark>1981</mark> -1	2-08	1981-1	2-08		Other			Spontaneous	
Serious	report?		Death:					Disabilit	y:	Congenital Anomaly:		
Ye	s		l	_ife Threat	ening:		Н	ospitalizatio	n: Yes	Other Me	dically Important Co	onditions:
Patient Informat	on											
Age	Gender		Height Weight				Report	Outcome				
18 Months	Male	84	84 Centimetres 11 Kilog			F	Recover	ed/resolved				
Link / Duplicate Report Information										_		
Record Type						Link AER*	* Numb	er				
No duplicate or lir	ked report.											
Product Informa	tion											
Product Desc	cription	Health Pr	oduct Role	Dosaç	ge Form	Route Administr		Dose	F	requency	Therapy Duration	Indication(s)
MMR II		Sus	Suspect LIQU SUBCUTA			Subcutaneous 0.5 mL						
Adverse Reaction	n Term					_						
	Ad	verse Reac	tion Term(s)			MedDRA Version					Reaction Duration	
Pyrexia							v.21	.1				

Reaction Duration

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Canada Vigilance
Summary of Reported Adverse Reactions

Report Information	n	**AE	ER = Adverse F	Reaction Re	eport								
Adverse Reaction Report Number		R Version	Initial Rece	ived Date	Latest Rece	ived Date	Source	e of Report	Autho	arket orization ER Number	Type of Report	Reporter Type	
000030603		0	1981-1	2-24	1981-1	2-24	(Other			Spontaneous		
Serious re	eport?			Death:			Disability:				Congenital Anomaly:		
Yes			L	ife Threat	ening:		H	ospitalizatio	n: Yes	Other Med	dically Important Co	onditions:	
Patient Information	on .												
Age	Gender		Height	V	Neight		Report	Outcome					
1 Years	Female					Unknown							
Link / Duplicate Report Information													
Record Type					Link AER** Number								
No duplicate or link	ked report.												
Product Informati	on												
Product Desci	ription	Health Pr	roduct Role	Dosag	je Form	Route Administr		Dose	Fre	equency	Therapy Duration	Indication(s)	
MMR	Suspect St			QUID FANEOUS	Subcutan	eous							
			NOT SF	PECIFIED	Oral								
Adverse Reaction Information	Term												

Adverse Reaction Term(s)

Febrile convulsion

Pyrexia

MedDRA Version

v.21.1

v.21.1

Canada Vigilanco

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Canada vignance
Summary of Reported Adverse Reactions

Cyanosis

Somnolence Stupor

Pallor

Report Information	on	**AE	R = Adverse F	Reaction Re	eport								
Adverse Reaction Report Number		ER Version mber	rsion Initial Received Date Late			eived Date	Sourc	e of Report	Market Authorization Holder AER Number		Type of Report	Reporter Type	
000030863		0	<mark>1982</mark> -01-19 198)1-19	19 Other				Spontaneous		
Serious r	eport?			ı	Death:			Disability:			Congenital Anomaly:		
Yes	3			_ife Threat	ening:		Н	ospitalizatio	n:	Other Med	dically Important Co	onditions:	
Patient Information	on												
Age	Gender		Height Weight				Report	Outcome					
1 Years	Male					Unknown							
Link / Duplicate F													
	Recor	d Type			Link AER** Number								
No duplicate or lin	ked report.												
Product Informat	ion									,			
Product Desc	ription	Health Pr	oduct Role	Dosag	je Form	Route Administr		Dose	Fr	equency	Therapy Duration	Indication(s)	
MEASLES VACCINE Suspect		spect	POWDER FOR SOLUTION SUBCUTANEOUS										
Adverse Reaction Information	n Term												
	Ad	verse Reac	tion Term(s)			MedDRA Version					Reaction Duration		

v.21.1

v.21.1 v.21.1

v.21.1

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Canada Vigilance
Summary of Reported Adverse Reactions

Report Informatio	n	**AE	R = Adverse R	eaction Re	eport							
Adverse Reaction Report Number		ER Version mber	Initial Receiv	ived Date	Source	ource of Report Authorization Holder AER Num			Type of Report	Reporter Type		
000030864		0	1982-01	-19	1982-0	1-19	(Other			Spontaneous	
Serious re	port?				Death:			Disabilit	y:		Congenital	Anomaly:
Yes			L	ife Threat	ening:		Н	ospitalizatio	n:	Other Med	dically Important Co	onditions:
Patient Information	on											
Age	Gender		Height	V	Veight		Report	Outcome				
22 Months	Female						Unl	nown				
Link / Duplicate Report Information												
	Recor	d Type				Link AER*	* Numb	er				
No duplicate or link	ed report.											
Product Informati	on											
Product Descr	ription	Health Pro	oduct Role	Dosag	je Form	Route Administr		Dose	Fre	equency	Therapy Duration	Indication(s)
ATTENUVAX		Sus	spect	NOT SF	PECIFIED							
Adverse Reaction Information	Term					_						
Adverse Reaction Term(s)						MedDRA Version					Reaction Duration	
Conjunctivitis						v.21.1						
Irritability						v.21.1						

v.21.1

v.21.1

v.21.1

Pharyngitis

Pyrexia

Rash

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Canada Vigilance	
Summary of Reported Adverse Reaction	ns

Report Information	n	**AEF	R = Adverse Re	eaction Re	eport							
Adverse Reaction Report Number		R Version nber			Source	e of Report	Market Authorization Holder AER Number		Type of Report	Reporter Type		
000030868	(0	<mark>1982</mark> -01-04 1982-0		1-04	(Other			Spontaneous		
Serious report?					Death:			Disabilit	y:		Congenital	Anomaly:
Yes			Li	fe Threat	ening:		H	ospitalizatio	n:	Other Med	dically Important Co	onditions:
Patient Information	on											
Age	Gender		Height	V	Veight		Report	Outcome				
14 Months	Female						Unknown					
Link / Duplicate R	eport Infor	mation										
	Record	d Type				Link AER*	* Numb	er				
No duplicate or link	ked report.											
Product Informati	on											
Product Desci	ription	Health Pro	oduct Role	Dosag	je Form	Route Administr		Dose	Fre	equency	Therapy Duration	Indication(s)
ASPIRIN		Drug used	to treat AE	NOT SF	PECIFIED	Oral						
MMR II		Sus	pect		QUID FANEOUS							
Adverse Reaction Information	Term											
	Adv	erse React	tion Term(s)			Me	dDRA	/ersion			Reaction Duration	

v.21.1

Pyrexia

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Report Informatio	n	**AE	R = Adverse F	Reaction Re	eport							
Adverse Reaction Report Number		R Version	Initial Received II:		ate Latest Received Date		Sourc	e of Report	Autho	arket orization ER Number	Type of Report	Reporter Type
000030876	(0	1982-0	1-04	1982-0	1-04		Other			Spontaneous	
Serious report?				Death:			Disabilit	y:		Congenital	Anomaly:	
Yes			l	₋ife Threat	ening:		Н	ospitalizatio	n: Yes	Other Me	dically Important Co	onditions:
Patient Informatio	on .											
Age	Gender	der Height We		Weight	Report Outcome							
1 Years	Female					Unknown						
Link / Duplicate R	eport Info	rmation										
	Recor	d Type			Link AER** Number							
No duplicate or link	ed report.											
Product Information	on											
Product Descr	ription	Health Pr	oduct Role	Dosag	ge Form	Route Administr		Dose	Fre	equency	Therapy Duration	Indication(s)
MMR II	MMR II Suspect SU			QUID TANEOUS								
Adverse Reaction Information	Term											
	Adv	verse Reac	tion Term(s)			Me	edDRA	Version			Reaction Duration	

Petechiae

Purpura Pura

v.21.1

v.21.1

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Summary of Reported Adverse Reactions

Report Information	on	**AE	R = Adverse F	Reaction Re	eport							
Adverse Reaction Report Number		ER Version mber	I INITIAL RECEIVED DA		Latest Received Date		Sourc	e of Report	Market Authorization Holder AER Number		Type of Report	Reporter Type
000030877		0	1982-0	1-12	1982-0	1-12		Other			Spontaneous	
Serious report?			Death:		Disability:		Congenital Anomaly:					
Yes	5			_ife Threat	ening:		Н	<u>ospitalizatio</u>	n:	Other Med	dically Important Co	onaitions:
Patient Informati	on											
Age	Gender		Height Weight				Report Outcome					
4 Years	Male						Unl	known				
Link / Duplicate I	Report Info	rmation										
•		d Type			Link AER** Number							
No duplicate or lin	ked report.											
Product Informat	tion											
Product Desc	ription	Health Pr	oduct Role	Dosag	je Form	Route Administr		Dose	Fre	equency	Therapy Duration	Indication(s)
MMR II		Sus	spect	LIC SUBCUT	QUID FANEOUS							
Adverse Reaction	n Term											
	Ad	verse Reac	tion Term(s)			Me	edDRA	Version			Reaction Duration	

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	

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Report Information	
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
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	

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Report Information

**AER = Adverse Reaction Report

React	Adverse tion Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date		Market Authorization Holder AER Number	Type of Report	Reporter Type
00	0030879	0	1982-01-12	1982-01-12	Other		Spontaneous	

Serious report?

Yes

Death:	Disability:	Congenital Anomaly:
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 Vigilanco

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

Cummary of Panartad Advarca Panations	
Summary of Reported Adverse Reactions	

Report Informatio	n	**AE	R = Adverse R	eaction Re	eport							
Adverse Reaction Report Number		ER Version nber	Initial Recei	ved Date	Latest Rece	eived Date	Sourc	e of Report	Auth	larket orization AER Number	Type of Report	Reporter Type
000030881		0	<mark>1982</mark> -01	I-12	1982-0	1-12		Other			Spontaneous	
Serious re	eport?			l	Death:			Disabilit	y:		Congenital	Anomaly:
Yes)		L	ife Threat	ening:		Н	ospitalizatio	n:	Other Med	dically Important Co	onditions:
Patient Information	on											
Age	Gender		Height	V	Weight		Report	Outcome				
18 Months	Male						Un	known				
Link / Duplicate R	eport Info	rmation										
	Recor	d Type				Link AER*	* Numb	er				
No duplicate or link	ed report.											
Product Informati	on											
Product Descr	ription	Health Pr	oduct Role	Dosag	ge Form	Route Administr		Dose	Fı	requency	Therapy Duration	Indication(s)
MMR II		Sus	spect		QUID TANEOUS							
Adverse Reaction Information	Term					_						
Adverse Reaction Term(s)				Me	dDRA	Version			Reaction Duration			
Pyrexia							v.21					
Rash							v.21	.1				

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 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
000031062	0	<mark>1982</mark> -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	

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Report Information	**AER = Adverse Reaction Report

Adve Reaction Num	Report	Latest AER Version Number	Initial Received Date	Latest Received Date		Market Authorization Holder AER Number	Type of Report	Reporter Type
00003	2052	0	<mark>1982</mark> -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

1 Todaot Illioilliation							
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 Vigilanca

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Canada vigilance	
Summary of Reported Adverse Reactions	3

Report Information	n	**AE	R = Adverse I	Reaction Re	eport							
Adverse Reaction Report Number		R Version				eived Date	ved Date Source of Report Author			larket orization AER Number	Type of Report	Reporter Type
000032424		0	1982-0	5-19	1982-0)5-19		Other			Spontaneous	
Serious re	port?				Death:			Disabilit	y:		Congenital	Anomaly:
Yes				Life Threat	ening:		Н	ospitalizatio	n:	Other Med	dically Important Co	onditions:
Patient Informatio	n											
Age	Gender		Height	1	Weight		Report	Outcome				
1 Years	Female					Recovered/resolved						
Link / Duplicate Ro	eport Info	rmation										
	Recor	d Type				Link AER** Number						
No duplicate or link	ed report.											
Product Information	on											
Product Descr	iption	Health Pr	oduct Role	Dosag	ge Form	Route Administr		Dose	Fr	requency	Therapy Duration	Indication(s)
MMR	MMR Suspect		spect	LIQUID SUBCUTANEOUS		Subcutan	eous					
Adverse Reaction Term Information												
	Adv	verse Reac	tion Term(s)			Me	edDRA	Version			Reaction Duration	
Face oedema							v.21					
Pyrexia	Pyrexia						v.21.1					

Rash

v.21.1

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A 237 Report(s)

Canada Vigilance
Summary of Reported Adverse Reactions

Report Information	n	**AE	R = Adverse F	Reaction Re	eport							
Adverse Reaction Report Number Adverse Latest AER Version Number		Initial Recei	nitial Received Date Latest Rece		eived Date Source of Re			Market Authorization Holder AER Number		Type of Report	Reporter Type	
000032432		0	1982-0	5-14	1982-0)5-14		Other			Spontaneous	
Serious re	eport?				Death:			Disabilit	y:		Congenital	Anomaly:
Yes			l	ife Threat	ening:		H	ospitalizatio	n:	Other Med	dically Important Co	onditions:
Patient Information	on .											
Age	Gender		Height	V	Veight		Report	Outcome				
15 Months	Male	81	Centimetres	12 k	Kilograms	F	Recover	ed/resolved				
Link / Duplicate R	eport Info	rmation										
	Recor	d Type			Link AER** Number							
No duplicate or link	ced report.											
Product Informati	on											
Product Desci	ription	Health Pr	oduct Role	Dosag	e Form	Route Administr		Dose	Fre	equency	Therapy Duration	Indication(s)
ASPIRIN		Drug used	to treat AE	NOT SP	ECIFIED	Oral						
MMR II		Sus	Suspect LIQUID SUBCUTANEOUS				0.5 mL					
Adverse Reaction Term Information												
	Ad	verse Reac	tion Term(s)			Me	dDRA	/ersion			Reaction Duration	

v.21.1

v.21.1

v.21.1

Irritability

Pyrexia

Rash

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Canada Vigilance
Summary of Reported Adverse Reactions

Report Information	n	**AE	R = Adverse I	Reaction Re	eport							
Adverse Reaction Report Number	leport Latest AER Version Initial Received Date La			Latest Rece	Received Date Source of Report			Market Authorization Holder AER Number		Type of Report	Reporter Type	
000032824		0	1982-0	06-28	1982-0	6-28		Other			Spontaneous	
Serious re	port?				Death:			Disabilit	y:		Congenital	Anomaly:
Yes				Life Threat	ening:		Н	ospitalizatio	n: Yes	Other Med	dically Important Co	onditions:
Patient Informatio	n											
Age	Gender		Height	V	Veight		Report	Outcome				
20 Months	Female					Unknown						
Link / Duplicate Ro	eport Info	rmation										
	Recor	d Type				Link AER** Number						
No duplicate or link	ed report.											
Product Information	on											
Product Descr	iption	Health Pr	oduct Role	Dosag	je Form	Route Administr		Dose	Fr	equency	Therapy Duration	Indication(s)
MMR		Sus	spect		QUID FANEOUS							
Adverse Reaction Information	Term											
	Ad	verse Reac	tion Term(s)			Me	dDRA	Version			Reaction Duration	
Dehydration							v.21					
Diabetes mellitus	<u> </u>						v.21	.1				

v.21.1 v.21.1

Py<u>rexia</u>

Respiratory disorder

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

Report Information	n	**AE	R = Adverse F	Reaction Re	eport							
Adverse Reaction Report Number		R Version	Initial Recei	ved Date	Latest Rece	eived Date	Sourc	e of Report	Market Authorization Holder AER Number		Type of Report	Reporter Type
000033608		0	1982-0	7-21	1982-0	7-21 Other				Spontaneous		
Serious re	port?		Death:			Disabilit	y:		Congenital	Anomaly:		
Yes			L	ife Threat	ening:		Н	ospitalizatio	n:	Other Med	onditions:	
Patient Information	n											
Age	Gender		Height	V	Neight		Report	Outcome				
19 Months	Female						Un	known				
Link / Duplicate Re	eport Info	rmation										
	Recor	d Type				Link AER*	* Numb	er				
No duplicate or linke	ed report.											
Product Information	on											
Product Descri	iption	Health Pro	oduct Role	Dosag	je Form	Route Administr		Dose	Fr	requency	Therapy Duration	Indication(s)
MMR II		Sus	spect		QUID FANEOUS							
Adverse Reaction Information	Term											
	Adv	verse Reac	tion Term(s)			Me	dDRA	Version			Reaction Duration	
Febrile convulsion							v.21					
Pyrexia							v.21	.1				

Reaction Duration

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Canada Vigilance
Summary of Reported Adverse Reactions

Report Informatio	n	**AE	R = Adverse Rea	action Re	eport									
Adverse Reaction Report Number	Latest AEI Num		Initial Receive	d Date	Latest Rece	ived Date	Sourc	e of Report	Aut	Market horization AER Number	Type of Report	Reporter Type		
000035146	C	1	1982-11-	15	1982-1	1-15		Other			Spontaneous			
Serious re	port?				Death:			Disabilit	y:		Congenital Anomaly			
Yes			Life	e Threat	ening:		Н	lospitalizatio	n: Yes	Other Me	dically Important Co	onditions:		
Patient Information	on .													
Age	Gender		Height	V	Veight		Report	Outcome						
20 Months	Female						Un	known						
Link / Duplicate R	eport Infor	mation												
	Record	Туре				Link AER*	* Numb	er						
No duplicate or link	ced report.													
Product Informati	on													
Product Descr	ription	Health Pr	oduct Role	Dosag	e Form	Route Administr		Dose	F	requency	Therapy Duration	Indication(s)		
ATTENUVAX		Sus	spect	NOT SP	ECIFIED									
Adverse Reaction Information	Term													

MedDRA Version

v.21.1

v.21.1

Adverse Reaction Term(s)

Pyrexia

Seizure

Canada Vigilance

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

Summary of Reported Adverse Reactions

Report Informati	on	**AE	R = Adverse R	Reaction Re	eport							
Adverse Reaction Report Number		ER Version mber	Initial Recei	ved Date	ate Latest Received Date		Source of	of Report	Autho	arket orization ER Number	Type of Report	Reporter Type
000036047		0	1983-03	3-24	1983-0	3-24	Ot	her			Spontaneous	Physician
Serious (L	ife Threat	Death: ening:		Hos	Disabilit pitalizatio		Other Med	Congenital	
Patient Informati	on											
Age	Gender		Height	V	Veight		Report O	utcome				
16 Months	Male					F	Recovered	/resolved				
Link / Duplicate	Report Info	rmation										
	Recor	rd Type				Link AER*	* Number					
No duplicate or lin	ked report.											
Product Informa	tion											
Product Desc	cription	Health Pr	oduct Role	Dosag	je Form	Route Administr		Dose	Fre	quency	Therapy Duration	Indication(s)
MMR II		Sus	spect		QUID FANEOUS							
Adverse Reaction	n Term											
	Adverse Reaction Term(s)					MedDRA Version					Reaction Duration	
Haemolytic anaer	nia 📁						v.21.1					

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

Report Information	on	**AE	R = Adverse R	eaction Re	eport									
Adverse Reaction Report Number		ER Version mber	Initial Receiv	ed Date	Latest Rec	eived Date	Sourc	e of Report	Market Authorization Holder AER Numb		Type of Report	Reporter Type		
000036267		0	1 <mark>983</mark> -01	-24	1983-0	01-24	1-24 Other				Spontaneous			
Serious r	eport?				Death:			Disabilit	y:		Congenital	Anomaly:		
Yes	3		L	ife Threat	ening:		Н	lospitalizatio	n:	Other Med	dically Important Co	onditions:		
Patient Information	on													
Age	Gender		Height	V	Veight		Report	Outcome						
1 Years	Male						Un	known						
Link / Duplicate F	Report Info	rmation												
	Recor	d Type				Link AER*	* Numb	er						
No duplicate or lin	ked report.													
Product Informat	ion													
Product Desc	ription	Health Pro	oduct Role	Dosag	je Form	Route Administr		Dose	Fr	equency	Therapy Duration	Indication(s)		
MMR II		Sus	spect		QUID ANEOUS									
Adverse Reaction Information	n Term											,		
	Ad	verse Reac	tion Term(s)			Me	edDRA	Version			Reaction Duration			
Pyrexia							v.21	1.1						
Seizure							v.21	1.1						

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

Canada Vigilance
Summary of Reported Adverse Reactions

Report Information	on	**AE	R = Adverse R	Reaction Re	eport							
Adverse Reaction Report Number		ER Version mber	r initial Receive		ate Latest Received Date		Source	of Report	Market Authorization Holder AER Number		Type of Report	Reporter Type
000037800		0	1983-02	2-24	1983-0	2-24	Ot	ther			Spontaneous	
Serious r	eport?			I	Death:			Disabilit	y:		Congenital	Anomaly:
Yes	3		L	ife Threat	ening:		Hos	pitalizatio	n:	Other Med	onditions:	
Patient Information	on											
Age	Gender		Height	V	Veight		Report O	utcome				
4 Years	Male						Unkn	own				
Link / Duplicate F	Report Info	rmation										
	Recor	d Type				Link AER*	* Number					
No duplicate or lin	ked report.											
Product Informat	ion											
Product Desc	ription	Health Pr	oduct Role	Dosag	je Form	Route Administr		Dose	Frequ	uency	Therapy Duration	Indication(s)
MMR II		Sus	spect		QUID FANEOUS							
Adverse Reaction Information	n Term											
	Adverse Reaction Term(s)					MedDRA Version					Reaction Duration	
Anaphylactic react	tion						v.21.1					

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Canada Vigilance
Summary of Reported Adverse Reactions

Report Information	on	**AE	R = Adverse R	eaction Re	eport									
Adverse Reaction Report Number		ER Version nber	Initial Receiv	ved Date	Latest Received Date		Sourc	e of Report	Market Authorization Holder AER Numl		Type of Report	Reporter Type		
000038036		0	<mark>1983</mark> -03	3-28	1983-0	03-28	3-28 Other				Spontaneous			
Serious r	eport?				Death:		Disability:				Congenital Anomaly:			
Yes			L	ife Threat	Threatening: Hospitalization:					Other Med	dically Important Co			
Patient Information	on													
Age	Gender		Height	1	Weight		Report	Outcome						
1 Years	Male						Un	known						
Link / Duplicate F	Report Info	rmation												
	Recor	d Type				Link AER*	* Numb	er						
No duplicate or lin	ked report.													
Product Informat	ion											_		
Product Desc	ription	Health Pr	oduct Role	Dosag	ge Form	Route Administr		Dose	Fr	equency	Therapy Duration	Indication(s)		
MMR II		Sus	spect		QUID TANEOUS									
Adverse Reaction Information	n Term													
	Ad	verse Reac	tion Term(s)			Me	edDRA	Version			Reaction Duration			
Pruritus							v.21	l <u>.1</u>						
Pyrexia							v.21	l.1						

v.21.1

v.21.1

Rash

Seizure

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

Report Informatio	n	**AE	R = Adverse F	Reaction Re	eport									
Adverse Reaction Report Number		R Version	er Initial Received Date Latest R			eived Date				Market norization AER Number	Type of Report	Reporter Type		
000038047	(0	1983-0	3-16	1983-0	3-16		Other			Spontaneous			
Serious re	port?				Death:			Disabilit	y:		Congenital	Anomaly:		
Yes			l	Life Threat	ening:		Н	ospitalizatio	n: Yes	Other Med	Other Medically Important Conditions:			
Patient Informatio	n													
Age	Gender		Height	١	Neight		Report	Outcome						
18 Months	Female						Un	known						
Link / Duplicate R	eport Info	rmation								_				
	Recor	d Type				Link AER*	* Numb	er						
No duplicate or link	ed report.													
Product Informati	on		,											
Product Descr	ription	Health Pr	oduct Role	Dosag	je Form	Route Administr		Dose	F	requency	Therapy Duration	Indication(s)		
MMR II		Sus	spect		QUID FANEOUS									
Adverse Reaction Information	Term													
	Adv	erse Reac	tion Term(s)			Me	edDRA	Version			Reaction Duration			
Encephalitis							v.21							
Meningitis							v.21	.1						

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

237 Report(s)

Adverse Reaction Report Number	Latest AER Version Number	Initial Receive	d Date	Latest Recei	ived Date	Sourc	e of Report	Market Authorization Holder AER Number		Type of Report	Reporter Type	
000039479	0	1983-07-2	20	1983-0	7-20		Other			Spontaneous		
Serious re	eport?		D	eath:			Disabilit	y:		Congenital	Anomaly:	
Yes		Life	Threate	ening:		Н	ospitalizatio	n: Yes	Other Med	Other Medically Important Conditions:		
Patient Information	on								_			
Age	Gender	Height	W	/eight		Report	Outcome					
15 Months	Female					Unl	known					
Link / Duplicate R	Report Information											
	Record Type				Link AER*	* Numb	er					
No duplicate or link	ked report.				<u>'</u>							
Product Informati	ion											
Product Descr		roduct Role	D	Form	Route	of	Dose	_	requency	Therapy Duration	Indication(s)	

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

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

Adverse Reaction Term

Report Runtime: Initial Received Date: Latest Received Date:

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Total Number of Reports:

Report Inf	ormation

**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
000040376	0	1 <mark>983</mark> -10-27	1983-10-27	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome	
18 Months	Male			Unknown	

Link / Duplicate Report Information

Link AER Number Record Type**

No duplicate or linked report.

Product Information

Product Description	Health Product Role	th Product Role Dosage Form		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	

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Report Information	n	**AE	R = Adverse R	eaction Re	port								
Adverse Reaction Report Number		ER Version mber	Initial Received Date Latest Recei		eived Date	Sourc	e of Report	Market Authorization Holder AER Number		Type of Report	Reporter Type		
000041543		0	1983-12-06 1983-12			12-06		Other			Spontaneous		
Serious report?				[Death:			Disabilit	y:		Congenital	Congenital Anomaly:	
Yes			L	ife Threate	ening:		Н	ospitalizatio	ation: Yes Other Medically Important Condition			onditions:	
Patient Information	on .												
Age	Gender		Height	V	Veight	Report Outcome							
18 Months	Female						Unknown						
Link / Duplicate R	eport Info	rmation											
	Recor	d Type				Link AER*	* Numb	er					
No duplicate or link	ced report.												
Product Informati	on												
Product Descr	ription	Health Pro	oduct Role	Dosag	e Form	Route Administr		Dose	Fre	equency	Therapy Duration	Indication(s)	
MMR II		Sus	spect		UID ANEOUS								
Adverse Reaction Information	Term												
	Ad	verse Reac	tion Term(s)			Me	dDRA	Version			Reaction Duration		
Pyrexia							v.21	.1					

v.21.1

Seizure

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Summary of Reported Adverse Reacti

Report Informati	on	**AE	R = Adverse F	Reaction Re	eport							
Adverse Reaction Report Number		ER Version mber	Initial Rece	ived Date	Latest Rece	eived Date	Sourc	e of Report	Autl	Market norization AER Number	Type of Report	Reporter Type
000042381		0	<mark>1984</mark> -01-23 1984-0			1-23		Other			Spontaneous	
Serious r	Serious report? Death:			Death:		Disability: Congenital Anomaly:				Anomaly:		
Yes	Yes Life Threatening:			ening:		Н	ospitalizatio	n: Yes	Other Medically Important Conditions:			
Patient Informati	on											
Age	Gender		Height	1	Weight		Report	Outcome				
15 Months				F	Recover	ed/resolved						
Link / Duplicate I	Report Info	rmation								_		
	Recor	d Type				Link AER*	* Numb	er				
No duplicate or lin	ked report.											
Product Informat	ion		,							,		
Product Desc	ription	Health Pr	oduct Role	Dosag	ge Form	Route Administr		Dose	F	requency	Therapy Duration	Indication(s)
MMR II		Sus	spect		QUID TANEOUS							
Adverse Reactio Information	n Term											
	Ad	verse Reac	tion Term(s)			Me	dDRA	Version			Reaction Duration	
Pyrexia						v.21						
Seizure	Seizure						v.21	.1				

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

_		
Panart	nformation	`

**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
000043305	0	<mark>1984</mark> -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	

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Report Informatio	n	**AE	R = Adverse R	eaction Re	eport							
Adverse Reaction Report Number	Latest AEF Num		Initial Receiv	ed Date	Latest Rece	eived Date	Sourc	e of Report	Auth	/larket norization AER Number	Type of Report	Reporter Type
000043908	0		1984-06	-22	1984-0	6-22		Other			Spontaneous	
Serious re	Serious report?			Į.	Death:			Disabilit	y:		Congenital	Anomaly:
Yes			Li	Life Threatening: Hospitalization:		n:	Other Me	dically Important Co	onditions:			
Patient Informatio	n									_		
Age	Gender		Height	V	Veight		Report	Outcome				
1 Years	Male						Un	known				
Link / Duplicate R	eport Inforr	nation										
	Record	Туре			Link AER** Number							
No duplicate or link	ed report.											
Product Information	Product Information											
Product Descr	iption	Health Pr	oduct Role	Dosag	je Form	Route Administr		Dose	F	requency	Therapy Duration	Indication(s)

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

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A 237 Report(s)

Canada Vigilance			
Summary of Reported Adverse Reactions			

Report Information		**AE	R = Adverse F	Reaction Re	eport							
Adverse Reaction Report Number	atest AE Nun	R Version nber	Initial Rece	ived Date	Latest Rece	ived Date	Sourc	e of Report	Auth	arket orization LER Number	Type of Report	Reporter Type
000044636	()	1984-1	1-12	1984-1	1-12	F	ospital			Spontaneous	
Serious repo	ort?			Death: Life Threatening:			Disability: Hospitalization:		Congenital Anomaly: Other Medically Important Conditions:			
Patient Information									·			
Age	Gender		Height	V	Neight		Report	Outcome				
1 Years	Female					Not	recover	<mark>ed/</mark> not resolve	ed			
Link / Duplicate Rep	Link / Duplicate Report Information											
	Record	d Type			Link AER** Number							
No duplicate or linked	d report.											
Product Information	n											
Product Descrip	otion	Health Pro	oduct Role	Dosag	je Form	Route Administr		Dose	Fr	equency	Therapy Duration	Indication(s)
MMR II		Sus	spect		QUID FANEOUS							
Adverse Reaction T Information	Term											
Adverse Reaction Term(s)			MedDRA Version				Reaction Duration					
Neutropenia =							v.21	.1				
Pyrexia							v.21	.1				

Rash

v.21.1

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Report Information

**AER = Adverse Reaction Report

R	Adverse eaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date		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(s)	MedDRA Version	Reaction Duration
Cellulitis	v.21.1	
Injection site reaction	v.21.1	
Pain	v.21.1	
Pyrexia	v.21.1	

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Report Information

**AER = Adverse Reaction Report

Adverse Reaction Re Number	Dort Latest AER Version Number	Initial Received Date	Latest Received Date		Market Authorization Holder AER Number	Type of Report	Reporter Type
00004778	3 0	1985-05-03	1985-05-03	Hospital		Spontaneous	

Serious report?

Death:	Disability:	Congenital Anomaly:
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(s)	MedDRA Version	Reaction Duration
Decreased appetite	v.21.1	
Pyrexia	v.21.1	
Rash	v.21.1	
Vomiting	v.21.1	

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

Summary of Reported	Adverse Reactions

Report Information	n	**AE	R = Adverse F	Reaction Re	eport							
Adverse Reaction Report Number		R Version	Initial Recei	ved Date	Latest Rece	ived Date	Sourc	e of Report	Auth	larket orization AER Number	Type of Report	Reporter Type
000048312		0	1985-0	7-03	1985-0	7-03		Other			Spontaneous	
Serious re	_		L	ife Threat	Death: ening:		Н	Disabilit ospitalizatio		Other Med	Congenital	
Patient Information	on											
Age	Gender		Height	\	Neight		Report	Outcome				
1 Years	Female					F	Recover	ed/resolved				
Link / Duplicate R	eport Info	rmation										
	Recor	d Type				Link AER*	* Numb	er				
No duplicate or link	ked report.											
Product Informati	ion											
Product Desci	ription	Health Pr	roduct Role	Dosag	je Form	Route Administr		Dose	Fı	requency	Therapy Duration	Indication(s)
MMR II		Su	spect		QUID FANEOUS							
Adverse Reaction Information	Term											
	Ad	verse Read	ction Term(s)			MedDRA Version				Reaction Duration		
Pharyngitis						v.21.1						
Rash							v.21	.1				

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Summary of Reported Adverse React

Pyrexia

Rash

Report Information	on	**AE	R = Adverse I	Reaction Re	eport							
Adverse Reaction Report Number		ER Version mber	Initial Rece	ived Date	Latest Rece	eived Date	Sourc	e of Report	Autho	arket orization ER Number	Type of Report	Reporter Type
000048403		0	1985-0	7-25	1985-0	7-25		Other			Spontaneous	
Serious re	eport?				Death:			Disabilit	y:		Congenital	Anomaly:
Yes	3			Life Threat	ening:		Н	ospitalizatio	n:	Other Med	dically Important Co	onditions:
Patient Information	on											
Age	Gender		Height	1	Neight		Report	Outcome				
15 Months	Male					F	Recover	ed/resolved				
Link / Duplicate Report Information												
	Recor	d Type				Link AER*	* Numb	er				
No duplicate or linl	ked report.											
Product Informat	ion											
Product Desc	ription	Health Pr	oduct Role	Dosag	je Form	Route Administr		Dose	Fre	equency	Therapy Duration	Indication(s)
MMR II		Sus	spect		QUID FANEOUS							
Adverse Reaction Information	n Term											
	Ad	verse Reac	tion Term(s)			Me	edDRA	Version			Reaction Duration	
Decreased appetit	Decreased appetite				v.21	.1						

v.21.1

v.21.1

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Report Information	n	
Adverse		

**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
000048724	0	1985-07-05	1985-07-05	Other		Spontaneous	

Serious report?	
Yes	

Death:	Disability:	Congenital Anomaly:
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(s)	MedDRA Version	Reaction Duration
Decreased appetite	v.21.1	
Pyrexia	v.21.1	

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Report Informat	ion	**AE	R = Adverse F	Reaction Re	eport							
Adverse Reaction Repo Number	TT .	ER Version mber	I Initial Received Date I Latest Received		eived Date	Source of Report Autho		larket orization AER Number	Type of Report	Reporter Type		
000048960		0	1985-0	9-16	1985-0)9-16		Other			Spontaneous	
Serious	report?				Death:			Disabilit	y:		Congenital	Anomaly:
	es		L	ife Threat	ening:		Н	ospitalizatio	n:	Other Med	dically Important Co	
Patient Information	tion											
Age	Gender		Height	١ ١			Report	Outcome				
16 Months	Male				Not recovered/not resolved							
Link / Duplicate	Report Info	rmation										
	Reco	rd Type				Link AER*	Link AER** Number					
No duplicate or li	nked report.											
Product Informa	ation											_
Product Des	cription	Health Pr	oduct Role	Dosag	ge Form	Route Administr		Dose	Fr	equency	Therapy Duration	Indication(s)
MMR II		Sus	spect		QUID FANEOUS							
Adverse Reaction	on Term											
	Ad	verse Reac	tion Term(s)			MedDRA Version					Reaction Duration	
Cough			v.21.1									
Otitis media				v.21	.1							

v.21.1

v.21.1

Pyrexia

Rash

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A 237 Report(s)

Canada Vigilance
Summary of Reported Adverse Reactions

Report Informatio	n	**AE	R = Adverse I	Reaction Re	eport							
Adverse Reaction Report Number		ER Version mber	on Initial Received Date Latest Rece		eived Date	ed Date Source of Report Aut		Auth	arket orization AER Number	Type of Report	Reporter Type	
000049222		0	<mark>1984</mark> -1	2-12	1984-1	2-12		Other			Spontaneous	
Serious re Yes	•		Disability: Hospitalization:			Congenital Anomaly: Other Medically Important Conditions:						
Patient Informatio	n											
Age	Gender		Height	\	Neight		Report	Outcome				
22 Months	Female						Un	known				
Link / Duplicate R	eport Info	rmation										
	Recor	d Type			Link AER** Number							
No duplicate or link	ed report.											
Product Informati	on											
Product Descr	ription	Health Pi	roduct Role	Dosag	je Form	Route Administr		Dose	Fr	equency	Therapy Duration	Indication(s)
MMR II		Su	spect		QUID FANEOUS							
Adverse Reaction Information	Term											
Adverse Reaction Term(s)				MedDRA Version				Reaction Duration				
Pyrexia						v.21.1						
Rash							v.21	.1				

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

Reaction Duration

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Report Information	on	**AE	R = Adverse F	Reaction Re	eport							
Adverse Reaction Report Number		ER Version mber	Initial Received Date Latest Received		eived Date	Source	of Report	Market Authorization Holder AER Number		Type of Report	Reporter Type	
000049268		0	1984-1	2-03	1984-1	2-03		Other			Spontaneous	
Serious r	eport?				Death:			Disabilit	y:		Congenital	Anomaly:
Yes	3		L	ife Threat	ening:		Но	spitalizatio	n:	Other Med	lically Important Co	onditions:
Patient Information	on											
Age	Gender		Height	1	Neight		Report	Outcome				
1 Years	Male		•		Kilograms	Recovered/resolved						
Link / Duplicate R	Report Info	rmation										
	Reco	rd Type			Link AER** Number							
No duplicate or lin	ked report.											
Product Informat	ion											
Product Desc	ription	Health Pr	oduct Role	Dosag	ge Form	Route Administr		Dose	Fre	equency	Therapy Duration	Indication(s)
ACETYLSALICYL	IC ACID	Drug used	d to treat AE	NOT SF	PECIFIED							
MMR II		Sus	Suspect SUB0		QUID FANEOUS			0.5 mL				
TYLENOL		Drug used			PECIFIED	Oral						
Adverse Reaction	n Term						•		•			

Information

Pyrexia

Rash

Adverse Reaction Term(s)

MedDRA Version

v.21.1

v.21.1

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 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
000050779	0	1985-04-24	1985-04-24	Other		Spontaneous	

Serious report?

Yes

Death:	Disability:	Congenital Anomaly:
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(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	

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

Canada Vigilance
Summary of Reported Adverse Reactions

Report Informati	**AER = Adverse Reaction Report											
Adverse Reaction Report Number		ER Version mber			ived Date	Source of Report Auth		Market Authorization Holder AER Number		Type of Report	Reporter Type	
000051000		0	1985-0	1-16	1985-0	1-16		Other			Spontaneous	
Serious i	report?				Death:			Disabilit	y:		Congenital	Anomaly:
Ye	s		l	_ife Threat	ening:		Нс	spitalizatio	n: Yes	Other Med	dically Important Co	onditions:
Patient Informati	on											
Age	Gender		Height	V	Veight		Report	Outcome				
16 Months	Female		Unknown				nown					
Link / Duplicate	Report Info	rmation										
	Recor	d Type				Link AER*	* Numbe	er				
No duplicate or lin	ked report.											
Product Informa	tion				_							,
Product Desc	cription	Health Pr	oduct Role	Dosag	je Form	Route Administr		Dose	Fre	equency	Therapy Duration	Indication(s)
MMR II		Sus	Suspect LIQUID SUBCUTANEOUS							1.0 Day(s)		
Adverse Reaction	n Term					_						
	Ad	verse Reac	tion Term(s)			MedDRA Version Reaction Duration						
Seizure							v.21.	1				

Canada Vigilanca

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

Canada vigilance
Summary of Reported Adverse Reactions

Report Information	on	**AE	R = Adverse R	Reaction Re	eport							
Adverse Reaction Report Number		ER Version mber			Latest Rece			Market Authorization Holder AER Number		Type of Report	Reporter Type	
000051006		0	1985-0	5-13	1985-0	5-13		Other			Spontaneous	
Serious r	eport?				Death:			Disabilit	y:		Congenital	Anomaly:
Yes			L	ife Threat	ening:		Н	ospitalizatio	n:	Other Med	dically Important Co	onditions:
Patient Information	on											
Age	Gender		Height	1	Weight		Report	Outcome				
17 Months	Male	81	Centimetres	11	Kilograms		Un	known				
Link / Duplicate Report Information												
	Recor	d Type				Link AER*	* Numb	er				
No duplicate or lin	ked report.											
Product Informat	ion											_
Product Desc	ription	Health Pr	roduct Role	Dosag	ge Form	Route Administr		Dose	Fı	requency	Therapy Duration	Indication(s)
MMR II	Suspect LIQUID SUBCUTANEOUS			Subcutan	eous							
Adverse Reaction Term Information												
Adverse Reaction Term(s)					Me	edDRA	Version			Reaction Duration		
Crying							v.21					
Rash	Rash						v.21	.1				

Canada Vigilanaa

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Canada Vigilance								
Summary of Reported Adverse Reactions								
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Report Information	on	**AE	R = Adverse F	Reaction Re	eport							
Adverse Reaction Report Number		ER Version mber	I INITIAL RACAIVAN II		e Latest Received Date		Sourc	e of Report	Market Authorization Holder AER Number		Type of Report	Reporter Type
000051029		0	1985-0	4-03	1985-0	04-03		Other			Spontaneous	
Serious r	eport?				Death:			Disabilit	y:		Congenital	Anomaly:
Yes	S		L	ife Threat	ening:		Н	lospitalizatio	n: Yes	Other Me	dically Important Co	onditions:
Patient Informati	on											
Age	Gender		Height	1	Weight		Report	Outcome				
19 Months	Female	82	82 Centimetres 14 Kilograms			Not recovered/not resolved						
Link / Duplicate I	Report Info	rmation										
	Reco	rd Type				Link AER*	* Numb	er				
No duplicate or lin	ked report.											
Product Informat	ion											
Product Desc	ription	Health P	roduct Role	Dosag	ge Form	Route Administr		Dose	Fr	equency	Therapy Duration	Indication(s)
MMR II		Su	Suspect LIQUID SUBCUTANEOU			Subcutan	Subcutaneous 0.5 mL			every 1 Day(s)	1.0 Day(s)	
Adverse Reactio Information	n Term											
	Ad	verse Read	ction Term(s)			MedDRA Version					Reaction Duration	
Balance disorder	투						v.21.1					

v.21.1

Pyrexia

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Report Information **AER = Adverse Reaction Report										
Adverse Reaction Report Number	Latest AER Ver Number	sion Initial Receive	d Date	Latest Rece	ived Date	Source of Report	Autho	arket orization ER Number	Type of Report	Reporter Type
000051038	0	<mark>1985</mark> -01-3	80	1985-0	1-30	Other			Spontaneous	
Serious r	Serious report?		Death:			Disabilit	:y:		Congenital	Anomaly:
Yes	S	Life	Threate	ening:		Hospitalizatio	n: Yes	Other Med	lically Important C	onditions:
Patient Information	on									
Age	Gender	Height	V	Veight		Report Outcome				
1 Years	Male	75 Centimetres	10 k	Kilograms	F	Recovered/resolved				

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

Dua duat	Information
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(s)	MedDRA Version	Reaction Duration
Febrile convulsion	v.21.1	

Canada Vigilanaa

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

Canada vigilance
Summary of Reported Adverse Reactions
-

Report Information	on	**AE	R = Adverse R	Reaction Re	eport							
Adverse Reaction Report Number		ER Version mber	Initial Recei	ved Date	Latest Rece	eived Date	Sourc	e of Report	Market Authorization Holder AER Number		Type of Report	Reporter Type
000051040		0	1985-05	5-03	1985-0	5-03		Other			Spontaneous	
Serious re	eport?				Death:			Disabilit	y:	Congenital A		Anomaly:
Yes			L	ife Threat	ening:		Н	lospitalizatio	n: Yes	Other Med	dically Important Co	onditions:
Patient Information	on											
Age	Gender		Height	١	Neight		Report	Outcome				
1 Years	Male	78	Centimetres	11	Kilograms	F	Recover	ed/resolved				
Link / Duplicate R	Report Info	rmation										
	Recor	d Type				Link AER*	* Numb	er				
No duplicate or line	ked report.											
Product Informat	ion							•				
Product Desc	ription	Health Pr	oduct Role	Dosag	je Form	Route Administr		Dose	Fi	requency	Therapy Duration	Indication(s)
MMR II	MMR II Suspect SUBO			QUID FANEOUS				1	every 1 Day(s)	1.0 Day(s)		
Adverse Reaction Information	n Term											
Adverse Reaction Term(s)				Me	edDRA	Version			Reaction Duration			
Pyrexia							v.21					
Seizure							v.21	1.1				

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

Reaction Duration

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Summary of Reported Adverse Reactions

Adverse Reaction Term(s)

Pyrexia

Seizure

Rash

Report Information **AER = Adverse Reaction Report												
Adverse Reaction Report Number		R Version	Initial Receiv	ed Date	Latest Rece	ived Date	Source o		Market Authorization Holder AER Number		Type of Report	Reporter Type
000051043		0	1985-06	-24	1985-0	6-24	Oth	ner			Spontaneous	
Serious re	eport?			Death:				Disability	y:		Congenital Anomaly:	
Yes	;		Li	fe Threat	ening:		Hosp	oitalizatio	n: Yes	Other Me	dically Important Co	onditions:
Patient Information	on											
Age	Gender		Height	V	Neight		Report Ou	ıtcome				
13 Months	Female	80	Centimetres	11 l	Kilograms	F	Recovered/i	resolved				
Link / Duplicate R	Report Info	rmation										
	Recor	d Type			Link AER** Number							
No duplicate or linl	ked report.											
Product Informat	ion											
Product Desc	ription	Health Pr	oduct Role	Dosag	je Form	Route Administr		Dose	Fr	equency	Therapy Duration	Indication(s)
MMR II Sus		spect	LIQUID SUBCUTANEOUS		Subcutan	eous			every 1 Day(s)	1.0 Day(s)		
Adverse Reaction Information	n Term											

MedDRA Version

v.21.1

v.21.1

v.21.1

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 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
000051044	0	1985-07-05	1985-07-05	Other		Spontaneous	

Serious report?			
Yes			

Death:	Disability:	Congenital Anomaly:
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(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 S

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Summary of Reported	Adverse Reactions

Drug used to treat AE

Report Information **AER = Adverse Reaction Report												
Adverse Reaction Report Number	Latest AER Numl		Initial Received Date Latest Receive		eived Date	Sourc	e of Report	Auth	larket orization \ER Number	Type of Report	Reporter Type	
000051045	0		1985-09)-23	1985-0	9-23		Other			Spontaneous	
Serious re	port?			I	Death:			Disabilit	y:		Congenital	Anomaly:
Yes			L	ife Threat	ening:		Н	ospitalizatio	n:	Other Me	dically Important Co	onditions:
Patient Information												
Age	Gender		Height	V	Neight	eight Report Outcome						
19 Months	Female	81	Centimetres	13 k	Kilograms	F	Recover	ed/resolved				
Link / Duplicate Re	eport Inforn	nation										
	Record	Туре			Link AER** Number							
No duplicate or link	ed report.											
Product Information	on											
Product Descri	iption	Health Pro	oduct Role	Dosag	je Form		Route of Administration Dose		Fr	equency	Therapy Duration	Indication(s)
MMR II		Sus	spect		QUID FANEOUS			0.5 mL	1	every 1 Day(s)	1.0 Day(s)	

Adverse	Reaction	Term
Informat	ion	

TYLENOL

Adverse Reaction To	erm(s)	MedDRA Version	Reaction Duration
Hypersensitivity =		v.21.1	
Pyrexia		v.21.1	

Oral

NOT SPECIFIED

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Canada Vigilance
Summary of Reported Adverse Reactions

Report Information	on	**AE	ER = Adverse R	eaction Re	eport							
Adverse Reaction Report Number		R Version nber	Initial Recei	ved Date	d Date Latest Recei		Sourc	e of Report	Market Authorization Holder AER Number		Type of Report	Reporter Type
000051046)	1985-10)-25	1985-1	0-25		Other			Spontaneous	
Serious r	erious report? Death:					Disabilit	y:	Congenital Anomaly:				
Yes	S		L	ife Threat	Threatening: Ho			ospitalizatio	n: Yes	Other Med	dically Important Co	onditions:
Patient Information												
Age	Gender		Height	١	Veight		Report	Outcome				
13 Months	Male	74	Centimetres	9 k	Cilograms	F	Recover	ed/resolved				
Link / Duplicate I	Report Infor	mation										
	Record	d Type				Link AER*	* Numb	er				
No duplicate or linked report.												
Product Informat	tion											
Product Description Health Product Role D			Dosag	je Form	Route Administr		Dose	Fr	equency	Therapy Duration	Indication(s)	

Adverse Reaction Term

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					

Information			
Adv	erse Reaction Term(s)	MedDRA Version	Reaction Duration
Dyspnoea =		v.21.1	
Oculogyric crisis		v.21.1	
Pyrexia		v.21.1	
Seizure		v.21.1	

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Report Information	on	**AE	R = Adverse I	Reaction Re	eport								
Adverse Reaction Report Number		R Version	Initial Received		Latest Received Date		Sourc	e of Report	Market Authorization Holder AER Number		Type of Report	Reporter Type	
000051819		0	1 <mark>985</mark> -0	6-04	1985-0	06-04		Other			Spontaneous		
Serious r	eport?				Death: Disability:				y:		Congenital	Anomaly:	
Yes	3			_ife Threat	ening:		Н	ospitalizatio	n:	Other Med	dically Important Co	onditions:	
Patient Information	on												
Age	Gender		Height	V	Weight Report Outcome								
1 Years	Male					Recovered/resolved							
Link / Duplicate F	Report Infor	rmation											
	Recor	d Type				Link AER** Number							
No duplicate or lin	ked report.												
Product Informat	ion												
Product Desc	ription	Health Pr	oduct Role	Dosag	e Form	Route Administr		Dose	Fre	equency	Therapy Duration	Indication(s)	
MMR II		Sus	Suspect LIQUID SUBCUTANEC							every 1 Day(s)	1.0 Day(s)		
Adverse Reaction Information	n Term												
Adverse Reaction Term(s)				Me	dDRA	Version			Reaction Duration				

v.21.1 v.21.1

v.21.1

v.21.1

v.21.1

Anaphylactoid reaction

Apnoea Dizziness

Pain

Pallor

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Report Information	n	**AE	R = Adverse F	Reaction Re	eport							
Adverse Reaction Report Number		ER Version mber	Initial Received Hate I I atest Received		eived Date	Sourc	e of Report Authori		larket orization AER Number	Type of Report	Reporter Type	
000051824		0	1985-0	5-22	1985-0	5-22		Other			Spontaneous	
Serious re Yes	Serious report? Peath: Life Threatening:					Disability: Cong Hospitalization: Other Medically Impor					Anomaly: onditions:	
Patient Informatio	n											
Age	Gender		Height	V	Veight			Outcome				
13 Months	Female						Unl	known				
Link / Duplicate Report Information												
	Recor	d Type				Link AER*	* Numb	er				
No duplicate or link	ed report.											
Product Information	on											_
Product Descri	iption	Health Pr	oduct Role	Dosag	je Form	Route Administr		Dose	Fr	equency	Therapy Duration	Indication(s)
MMR II		Sus	spect	ect LIQUID SUBCUTANEOUS						every 1 Day(s)	1.0 Day(s)	
Adverse Reaction Term Information												
Adverse Reaction Term(s)					Me	MedDRA Version			Reaction Duration			
Cough						v.21.1						
Decreased appetite)					v.21.1						

Irritability

Pyrexia

v.21.1

v.21.1

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Report Information **AER = Adverse Reaction Report												
Adverse Reaction Report Number	Latest AEF Num		Initial Received Date Latest Rec		Latest Rece	ived Date	Source	urce of Report Auth		Market orization AER Number	Type of Report	Reporter Type
000051829	0		1985-05	-30	1985-0	5-30	(Other			Spontaneous	
Serious re	port?				Death:			Disabilit	y:		Congenital	Anomaly:
Yes	<u> </u>		Li	fe Threat	ening:		Н	ospitalizatio	n:	Other Med	dically Important C	onditions:
Patient Information												
Age	Gender	Height		V	Weight			Report Outcome				
6 Years	Male						Unknown					
Link / Duplicate Re	eport Inforn	mation										
	Record	Туре			Link AER** Number							
No duplicate or link	ed report.											
Product Information												_
Product Descri	iption	Health Pr	oduct Role	Dosag	je Form	Route Administr		Dose	Fı	requency	Therapy Duration	Indication(s)
MMR II		Sus	spect		QUID FANEOUS				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	

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Report Information	
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**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
000051850	0	1985-02-28	1985-02-28	Other		Spontaneous	

Serious report? Yes

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
2 Years	Male			Unknown

Link / Duplicate Report Information

Link AER Number Record Type**

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(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	
F	·	

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 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
000051859	0	1985-10-11	1985-10-11	Other		Spontaneous	

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

2019-03-07_exportPDF.pdf

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

Canada Vigilance
Summary of Reported Adverse Reactions

Report Informatio	n	**AE	R = Adverse I	Reaction Re	eport							
Adverse Reaction Report Number	Latest AE		Initial Rece	ived Date	Latest Rece	ived Date	Sourc	e of Report		Market thorization r AER Number	Type of Report	Reporter Type
000051862	C)	1985-0	8-21	1985-0	8-21		Other			Spontaneous	
Serious report?				Death:			Disabilit	ty:		Congenital	Anomaly:	
Yes				Life Threat	ening:		Н	lospitalizatio	n: Ye	S Other Me	dically Important Co	onditions:
Patient Information	n											
Age	Gender		Height	V	Veight		Report	Outcome				
1 Years Male				Unknown								
Link / Duplicate R	eport Infor	mation								_		
	Record	d Туре				Link AER*	* Numb	er				
No duplicate or link	ed report.											
Product Informati	on				_							
Product Descr	iption	Health Pr	oduct Role	Dosag	je Form	Route Administr		Dose		Frequency	Therapy Duration	Indication(s)
MMR II		Sus	spect		QUID FANEOUS					1 every 1 Day(s)	1.0 Day(s)	
Adverse Reaction Information	Term											
	Adverse Reaction Term(s)				MedDRA Version			Reaction Duration				
Generalised tonic-	clonic seizui	re =					v.21					
Syncope							v.21	1.1				

Canada Vigilanco

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Summa	ary of Reported Adverse Reactions
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Lymphadenopathy

Pyrexia

Seizure

Rash

Report Information	n	**AE	R = Adverse F	Reaction Re	eport							
Adverse Reaction Report Number		R Version	Initial Recei	ived Date	Latest Rece	ived Date	Source	e of Report	Auth	arket orization ER Number	Type of Report	Reporter Type
000051865		0	1985-0	7-15	1985-0	7-15	(Other			Spontaneous	
Serious report?		ı	Death:			Disabilit	y:		Congenital	Anomaly:		
Yes			L	ife Threat	ening:		Н	ospitalizatio	n: Yes	Other Med	dically Important Co	onditions:
Patient Information	on											
Age	Gender		Height	V	Veight		Report	Outcome				
16 Months					U		Unk	nknown				
Link / Duplicate R	Report Info	rmation										
_	Recor	d Type			Link AER** Number							
No duplicate or line	ked report.											
Product Informat	ion											_
Product Desc	ription	Health Pr	oduct Role	Dosag	je Form	Route Administr		Dose	Fr	equency	Therapy Duration	Indication(s)
MMR II		Sus	spect		QUID FANEOUS					every 1 Day(s)	1.0 Day(s)	
Adverse Reaction Information	n Term											
	Adv	erse Reac	tion Term(s)			Me	dDRA V	/ersion			Reaction Duration	

v.21.1

v.21.1

v.21.1 v.21.1

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

D 1	Information	
Report	Intormation	

**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
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(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	

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 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
000051867	0	1985-07-29	1985-07-29	Other		Spontaneous	

Serious report?

Death:

Disability:

Congenital Anomaly:

Hospitalization:

Other Medically Important Conditions:

Patient Information

L					
	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(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	

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Canada Vigilance
Summary of Reported Adverse Reactions

Report Informatio	n	**AE	R = Adverse F	Reaction Re	eport								
Adverse Reaction Report Number	Latest AE Num	R Version nber	Initial Recei	ved Date	Latest Rece	ived Date	Source	rce of Report Authori		arket orization AER Number	Type of Report	Reporter Type	
000051871	C)	1985-0	7-30	1985-0	(Other			Spontaneous			
Serious re	port?			ı	Death:			Disabilit	y:		Congenital	Anomaly:	
Yes			L	ife Threat	ening:		Н	ospitalizatio	n: Yes	Other Med	Medically Important Conditions:		
Patient Information	on												
Age	Gender		Height	V	Neight		Report	Outcome					
18 Months	Female					Unknown							
Link / Duplicate R	eport Infor	mation											
	Record	d Туре			Link AER** Number								
No duplicate or link	ed report.												
Product Informati	on												
Product Descr	ription	Health Pr	oduct Role	Dosag	je Form	Route Administr		Dose	Fre	equency	Therapy Duration	Indication(s)	
MMR II	Suspect			QUID FANEOUS					every 1 Day(s)	1.0 Day(s)			
Adverse Reaction Information	Adverse Reaction Term Information												
	Adverse Reaction Term(s)						edDRA \	Version			Reaction Duration		

Decreased appetite

Pyrexia

Rash

v.21.1

v.21.1 v.21.1

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

Adverse Reaction Report Number		ER Version mber	I INITIAL RECEIVED LI		ved Date Latest Received				Market Authorization Holder AER Number		Type of Report	Reporter Type	
000053305		0	1986-0	3-20	1986-0	3-20	0	ther			Spontaneous		
Serious re	eport?				Death:			Disabilit	y:		Congenital	Anomaly:	
Yes	1		ı	ife Threat	ening:		Но	spitalizatio	n: Yes	Other Medically Important Conditions:			
Patient Information	on												
Age	Gender		Height	V	Weight Report Outcome								
16 Months	Female				Recovered/resolved								
Link / Duplicate R	Report Info	rmation											
	Reco	d Type			Link AER** Number								
No duplicate or lin	ked report.												
Product Informat	ion												
Product Description Health Produ		roduct Role	Dosag	Dosage Form		of ration	Dose	Fre	equency	Therapy Duration	Indication(s)		
MMR II Suspect St				QUID ANEOUS	Subcutan	eous	0.5 mL		every 1 Day(s)	1.0 Day(s)			

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

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

Report Information	n	**AE	FR = Adverse F	Reaction Re	eport								
Adverse Reaction Report Number		ER Version mber	I INITIAL RACALVAN I		d Date Latest Received Date		Source	e of Report	Market Authorization Holder AER Number		Type of Report	Reporter Type	
000055017		0	1986-0	3-25	1986-0)3-25	(Other			Spontaneous		
Serious re	port?				Death: Disability:						Congenital	Anomaly:	
Yes			l	ife Threat	ening:		Н	ospitalizatio	n: Yes	Other Medically Important Conditions:			
Patient Information	n												
Age	Gender		Height	١ ١	Weight Report Outcome								
12 Months	Female					Unknown							
Link / Duplicate R	eport Info	rmation											
	Recor	d Type			Link AER** Number								
No duplicate or link	ed report.												
Product Informati	on												
Product Desci	Product Description Health Product Role		Dosag	Dosage Form		of ration	Dose	Frequency		Therapy Duration	Indication(s)		
MMR II	MMR II Suspect SU				QUID FANEOUS								
Adverse Reaction Information	Term												

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	

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

Report Information	n	**AE	R = Adverse F	Reaction Re	eport							
Adverse Reaction Report Number		R Version							Market Authorization Holder AER Number		Type of Report	Reporter Type
000055218		0	1986-02-18 1986-02					Other			Spontaneous	
Serious re	port?				Death:			Disabilit	y:		Congenital	Anomaly:
Yes			L	ife Threat	ening:		Н	ospitalizatio	n: Yes	Other Med	dically Important Co	onditions:
Patient Informatio	n											
Age	Gender		Height	V	Neight		Report	Outcome				
7 Months	Female						Un	known				
Link / Duplicate Re	eport Info	rmation										
	Recor	d Type				Link AER*	* Numb	er				
No duplicate or link	ed report.											
Product Information	on											,
Product Descri	iption	Health Pr	oduct Role	Dosag	ge Form	Route Administr		Dose	Fr	requency	Therapy Duration	Indication(s)
MMR II		Sus	spect		LIQUID JBCUTANEOUS							
Adverse Reaction Term Information												
	Ad	verse Reac	tion Term(s)			Me	dDRA	Version			Reaction Duration	
Dizziness							v.21					
Pyrexia			v.21	.1								

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Report Informati	on	**AE	R = Adverse R	eaction Re	eport							
Adverse Reaction Report Number		ER Version mber	Initial Recei	ved Date	Date Latest Received Date			e of Report	Autho	arket orization ER Number	Type of Report	Reporter Type
000055353		0	<mark>1986</mark> -0	1986-0)6-18		Other			Spontaneous		
Serious	report?			ı	Death:			Disabilit	y:		Congenital	Anomaly:
Ye	S		L	ife Threat	ening:		Н	ospitalizatio	n: Yes	Other Me	dically Important Co	onditions:
Patient Informati	ion											
Age	Gender		Height	\	Neight		Report	Outcome				
20 Months	Male	77	Centimetres	Kilograms	F	Recover	ed/resolved					
Link / Duplicate	Report Info	rmation										
	Reco	rd Type				Link AER*	* Numb	er				
No duplicate or lin	nked report.											
Product Informa	tion											
Product Desc	cription	Health Pr	oduct Role	Dosag	je Form	Route Administr		Dose	Fre	equency	Therapy Duration	Indication(s)
MMR II		Sus	uspect LIQUID SUBCUTANEOUS		Subcutan	neous 0.5 mL						
Adverse Reaction	n Term											
	Ad	lverse Reac	tion Term(s)			Me	edDRA	Version			Reaction Duration	
Gastroenteritis							v.21	.1				

v.21.1 v.21.1

v.21.1

Pyrexia

Rash Seizure

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 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
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

i ioaaot iiiioiiiiatioii							
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	

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

Reaction Duration

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Summary of Reported	Adverse Reactions
•	

Adverse Reaction Term(s)

Pyrexia

Seizure

Report Informatio	**AER = Adverse Reaction Report											
Adverse Reaction Report Number	ction Report Latest AER Version		Initial Rece	nitial Received Date Latest R		Latest Received Date		e of Report	Market Authorization Holder AER Number		Type of Report	Reporter Type
000055375	0		1986-0	2-10	1986-0	2-10	(Other	her		Spontaneous	
Serious re	eport?				Death:		Disability:		y:	Congenital Anomaly:		
Yes				Life Threat	ening:		Н	ospitalizatio	n: Yes	Other Me	dically Important Co	onditions:
Patient Information												
Age			l v	Weight Report Outcome								
1 Years	Male				Recovered/resolved with sequelae			uelae				
Link / Duplicate R	eport Inform	ation										
	Record	Туре			Link AER** Number							
No duplicate or link	ked report.											
Product Informati	on											
Product Descr	ription	lealth Pr	oduct Role	Dosag	je Form	Route Administr		Dose	Fre	equency	Therapy Duration	Indication(s)
MMR II Suspect		spect		QUID FANEOUS								
PHENOBARBITAL	PHENOBARBITAL Drug used to treat AE		NOT SF	PECIFIED								
Adverse Reaction Information	Term					_						

MedDRA Version

v.21.1 v.21.1

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

Canada Vigilance
Summary of Reported Adverse Reactions

Report Informati	Report Information **AER = Adverse Reaction Report											
Adverse Reaction Report Number		ER Version mber	Initial Recei	ived Date	Latest Rece	eived Date	Sourc	e of Report	Autl	Market norization AER Number	Type of Report	Reporter Type
000055431		0	1986-04-14 Other			Spontaneous						
Serious i	report?				Death:			Disabilit	y:	Congenital Anomaly:		
Ye	s		L	_ife Threat	tening:		Н	ospitalizatio	n: Yes	Other Me	dically Important Co	onditions:
Patient Informati	on											
Age	Gender		Height	1	Weight		Report	Outcome				
14 Months			Kilograms	F	Recovered/resolved							
Link / Duplicate	Report Info	rmation								_		
	Recor	d Type				Link AER** Number						
No duplicate or lin	ked report.											
Product Informa	tion											
Product Desc	cription	Health Pr	oduct Role	Dosag	ge Form	Route Administr		Dose	F	requency	Therapy Duration	Indication(s)
MMR II		Sus	Suspect LIQUID SUBCUTANEOUS			Subcutan	eous	0.5 mL				
Adverse Reaction	n Term											
	Ad	verse Reac	tion Term(s)			Me	edDRA	Version			Reaction Duration	
Pyrexia							v.21	.1				

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

Report Information **AER = Adverse Reaction Report												
Adverse Reaction Report Number	Latest AEI Num	_	version Initial Received Date Latest Received Date Source of Report Auth		Market norization AER Number	Type of Report	Reporter Type					
000057286	0		1986-08	-14	1986-0	08-14		Other			Spontaneous	
Serious re	eport?			ı	Death:		Disability:			Congenital Anomaly:		
Yes			Li	fe Threat	ening:	Hospitalization:		n:	Other Medically Important Conditions:			
Patient Information												
Age			V	Weight Report Outcome								
14 Months	Male						Unl	known				
Link / Duplicate R	eport Infor	mation										
	Record	Туре			Link AER** Number							
No duplicate or link	ked report.											
Product Informati	on											
Product Desci	Product Description Health Product Role		Dosag	je Form	Route Administ		Dose	Fı	requency	Therapy Duration	Indication(s)	
MMR II	MMR II Suspect		spect		QUID TANEOUS							
Adverse Reaction Information	Term											

Information			
Advers	e 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

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

	Summary of Reported Adverse Reactions	Latest Rece Total Number o
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
000057594	0	1 <mark>986</mark> -11-04	1986-11-04	Other		Spontaneous	
Serious re	nort?	-	Death: Ves	Disahilit	v.	Congenital	Anomaly:

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

Patient Information	tion			
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					

Adverse Reaction Term Information			
Advers	se Reaction Term(s)	MedDRA Version	Reaction Duration
Death =		v.21.1	
Encephalopathy		v.21.1	
Seizure		v.21.1	

Canada Vigilanaa

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

Canada vigilance							
Summary of Reported Adverse Reactions							
-							

Report Informatio	n	**AE	R = Adverse F	Reaction Re	eport							
Adverse Reaction Report Number		ER Version mber	Initial Recei	ved Date	Latest Rece	eived Date	Sourc	e of Report	Auth	larket orization AER Number	Type of Report	Reporter Type
000057676		0	1986-1	1-17	1986-1	1-17		Other			Spontaneous	
Serious re	port?				Death:			Disabilit	y:		Congenital	Anomaly:
Yes			L	ife Threat	ening:		Н	ospitalizatio	n: Yes	Other Med	dically Important Co	onditions:
Patient Informatio	n											
Age	Gender		Height	1			Report	Outcome				
12 Months	Male	76	Centimetres	11	Kilograms	F		ed/resolved				
Link / Duplicate R	eport Info	rmation										
•	Recor	d Type				Link AER*	* Numb	er				
No duplicate or link	ed report.											
Product Information	on											
Product Descr	iption	Health Pr	oduct Role	Dosag	ge Form	Route Administr		Dose	Fr	requency	Therapy Duration	Indication(s)
MMR II		Sus	spect		QUID FANEOUS	Subcutan	eous	0.5 mL				
Adverse Reaction Information	Term											
	Adverse Reaction Term(s)				Me	edDRA	Version			Reaction Duration		
Fatigue							v.21					
Somnolence							v.21	.1				

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Report Information **AER = Adverse Reaction Report												
Adverse Reaction Report Number	Latest AEF Num	_	Initial Recei	ved Date	Latest Rece	ived Date	Source	e of Report	Market Authorization Holder AER Numb		Type of Report	Reporter Type
000057694	0		<mark>1986</mark> -12	2-18	1986-1	2-18	(Other			Spontaneous	
Serious re	port?				Death:			Disabilit	y:		Congenital	Anomaly:
Yes			L	ife Threat	ening:		Н	ospitalizatio	n:	Other Med	dically Important Co	onditions:
Patient Informatio	n											
Age	Gender		Height	\	Weight		Report Outcome					
1 Years	Male						Unk	nown				
Link / Duplicate Re	eport Inforr	mation										
	Record	Туре				Link AER*	* Numb	er				
No duplicate or link	ed report.											
Product Information	on											
Product Descr	iption	Health Pro	oduct Role	Dosag	ge Form	Route Administr		Dose	Fı	requency	Therapy Duration	Indication(s)
ACETAMINOPHEN	ı	Drug used	to treat AE	NOT SF	PECIFIED	Oral			6	S every 1 Day(s)		

Adverse	Reaction	Term
Informati	on	

MMR II

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	

Subcutaneous

LIQUID SUBCUTANEOUS

Suspect

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Summary of Reported Adverse Reaction

Report Informatio	on **/	IER = Adverse Rea	ction Re	eport						
Adverse Reaction Report Number	Latest AER Version	Initial Receive	d Date	Pate Latest Received Date		Source of Report	Market Authorization Holder AER Number		Type of Report	Reporter Type
000057699	0	<mark>1986</mark> -12-1	6	1986-1	2-16	Other			Spontaneous	
Serious re	eport?	Death: Disab		Disabilit	ty:		Congenital	Anomaly:		
Yes		Life	Threat	hreatening: Hospita		Hospitalizatio	n:	Other Medically Important Conditions:		onditions:
Patient Information	on									
Age	Gender	Height	V	Neight		Report Outcome				
19 Months	Male	5 Centimetres	10 H	0 Kilograms Recovered/resolved						
Link / Duplicate R	eport Information									

Draduat	Information
Product	intormation

No duplicate or linked report.

Record Type

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				

Link AER** Number

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	

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

**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
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	

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

Report Informatio	n	**AE	R = Adverse R	eaction Re	port							
Adverse Reaction Report Number		R Version	Initial Receiv	ved Date	Latest Rece	eived Date	Sourc	e of Report	Auth	Market norization AER Number	Type of Report	Reporter Type
000058235		0	1987-02	2-09	1987-0)2-09	F	lospital			Spontaneous	
Serious report? Yes Life Th			Death: Disability: hreatening: Hospitalization:			Congenital Anomaly: es Other Medically Important Conditions:						
Patient Information	n											
Age	Gender		Height	V	Veight		Report	Outcome				
1 Years	Male						Un	known				
Link / Duplicate R	eport Info	rmation										
	Recor	d Type				Link AER*	* Numb	er				
No duplicate or link	ed report.											
Product Informati	on											_
Product Descr	ription	Health Pr	oduct Role	Dosag	e Form	Route Administr		Dose	F	requency	Therapy Duration	Indication(s)
TRIVIRIX 📃		Sus	spect		UID ANEOUS	Subcutan	eous	0.5 mL	1	l every 1 Day(s)		
Adverse Reaction Information	Term											
	Ad	verse Reac	tion Term(s)			MedDRA Version				Reaction Duration		
Anaphylactoid read	ction						v.21	.1				
Cyanosis	=					v.21.1						
Dyspnoea =							v.21	.1				

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Report Informa	tion	**AE	R = Adverse	Reaction Re	eport
Adverse Reaction Repo Number	rt	ER Version	Initial Rece	eived Date	Late
000059341		0	1987-	01-30	
Serious				Death	
Y	es			Life Threat	ening
Patient Informa	tion				
Age	Gender		Height	\	Neigl
1 Years	Female				
Link / Duplicate	Report Info	rmation			
	Recor	d Type			
No duplicate or I	inked report.				
Product Inform	ation				
Product Des	scription	Health P	roduct Role	Dosag	je Fo

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date		Market Authorization Holder AER Number	Type of Report	Reporter Type
000059341	0	1987-01-30	1987-01-30	Other		Spontaneous	

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

Patient informa	lion			
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 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	

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

ort Informa	atio	n		
Adverse action Repo Number	ort	Lates		
000059372				
Serious report?				
١	'es			
Patient Information				
ient Informa	atio	<u>n</u>		
Age	atio	n Gen		
	Adverse action Repo Number 000059372 Serious	action Report Number 000059372 Serious re Yes		

**AER = Adverse Reaction Repor	rt
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Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date		Market Authorization Holder AER Number	Type of Report	Reporter Type
000059372	0	1987 -03-27	1987-03-27	Other		Spontaneous	

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

Patient	Information

Age	Gender	Height	Weight	Report Outcome
1 Years	Male			Unknown

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

Product Information

i roduct imormation							
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	

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

Report Informatio	n	**AE	R = Adverse R	eaction Re	eport							
Adverse Reaction Report Number Reaction Report Number Latest AER Version Number Initial Received		ved Date	Date Latest Received Date S		Sourc	e of Report	Market Authorization Holder AER Number		Type of Report	Reporter Type		
000059612		0	<mark>1987</mark> -0	1-05	1987-0	1-05		Other			Spontaneous	
Serious re	port?				Death:			Disabilit	y:		Congenital	Anomaly:
Yes			L	ife Threat	ening:		Н	ospitalizatio	n:	Other Med	dically Important Co	onditions: Yes
Patient Informatio	n											
Age	Gender		Height	\	Neight		Report	Outcome				
15 Months	Female					F	Recover	ed/resolved				
Link / Duplicate R	eport Info	rmation										
	Recor	d Type				Link AER*	* Numb	er				
No duplicate or link	ed report.											
Product Information	on											
Product Descr	iption	Health Pr	oduct Role	Dosag	ge Form	Route Administr		Dose	Fr	equency	Therapy Duration	Indication(s)
TRIVIRIX		Sus	spect		QUID FANEOUS	Subcutan	eous	0.5 mL	1	every 1 Day(s)	1.0 Day(s)	
Adverse Reaction Information	Term											
	Ad	verse Reac	tion Term(s)			Me	edDRA	Version			Reaction Duration	
Parotid gland enlar	gement	<u> </u>					v.21	.1				
Pyrexia							v.21	.1				

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

Report Informatio	n	**AE	R = Adverse R	eaction Re	eport							
Adverse Reaction Report Number		R Version	Initial Receiv	ed Date	Latest Rece	eived Date	Sourc	e of Report	Auth	larket orization AER Number	Type of Report	Reporter Type
000059614		0	<mark>1987</mark> -01	-05	1987-0)1-05		Other			Spontaneous	
Serious re	eport?				Death:			Disabilit	y:		Congenital	Anomaly:
Yes			Li	fe Threat	ening:		Н	ospitalizatio	n:	Other Med	dically Important Co	onditions: Yes
Patient Informatio	on .											
Age	Gender		Height	V	Veight		Report	Outcome				
18 Months	Male						Un	known				
Link / Duplicate R	eport Info	rmation										
	Recor	d Type			Link AER** Number							
No duplicate or link	ked report.											
Product Informati	on											
Product Descr	ription	Health Pro	oduct Role	Dosag	je Form	Route Administr		Dose	Fr	equency	Therapy Duration	Indication(s)
TRIVIRIX		Sus	spect		UID ANEOUS			0.5 mL				
Adverse Reaction Information	Term											
	Adv	erse Reac	tion Term(s)			Me	dDRA	Version			Reaction Duration	
Parotitis 📃							v.21	.1			·	
Pyrexia							v.21	.1				

Canada Vigilance

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

Summary of Reported Adverse Reactions

Adverse Reaction Repor		R Version	Initial Recei	ved Date	Latest Rece	eived Date	Source	of Report	Marke Authoriza		Type of Report	Reporter	Type
Number	Nun	nber					o o un o o	- CI HOPOIT	Holder AER I			пороно	. , , ,
000059870		0	1987-0	1-30	1987-0	01-30		Other			Spontaneous		
Serious	report?			I	Death: Dis			Disabilit	cy: Congenital Anomaly:				
Ye	S		L	ife Threat	ening:		Но	spitalizatio	n: O	ther Med	dically Important Co		Yes
Patient Informat	on												
Age	Gender		Height	١ ١	Neight		Report	Outcome					
1 Years	Female		<u> </u>			F	-	d/resolved					
Link / Duplicate	Report Infor	mation											
,	•	d Type			Link AER** Number								
No duplicate or lin	nked report.												
Product Informa	tion												
Product Desc	cription	Health Pr	oduct Role	Dosag	je Form	Route Administr		Dose	Freque	ency	Therapy Duration	Indication	on(s)
MMR II Suspect St			QUID FANEOUS	Subcutan	eous		1 ever Day(1.0 Day(s)				

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	

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Adverse Reaction Report Number	Latest AER V Numbe	ersion	R = Adverse Rea	
000059892	0		<mark>1987</mark> -01-2	20
Serious re	eport?			
Yes			Life	Th
Patient Information	n			
Age	Gender		Height	
1 Years	Female			
Link / Duplicate R	eport Informa	tion		
	Record Ty	/pe		

Adverse Reaction Report

Date	Latest Received Date		Market Authorization Holder AER Number	Type of Report	Reporter Type
	1987-01-20	Other		Spontaneous	

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

Weight	Report Outcome
	Unknown

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

Product Information

i ioaast iiiisiiiatisii							
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	

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

Report Information	า	**AEI	R = Adverse R	eaction Re	eport							
Adverse Reaction Report Number	Latest AER Numl		Initial Received Date Latest Received		eived Date	Source	e of Report	Market Ort Authorization Holder AER Num		Type of Report	Reporter Type	
000060077	0		1 <mark>98</mark> 7-02	2-20	1987-0)2-20	(Other			Spontaneous	
Serious rep	port?				Death:			Disabilit	y:		Congenital	Anomaly:
Yes			L	ife Threat	ening:		H	ospitalizatio	n:	Other Med	dically Important Co	onditions: Yes
Patient Information	n											
Age	Gender		Height	١	Neight		Report	Outcome				
6 Years	Female						Unknown					
Link / Duplicate Re	eport Inforn	nation										
	Record	Туре			Link AER** Number							
No duplicate or linke	ed report.											
Product Information	on											
Product Descri	ption	Health Pro	oduct Role	Dosag	je Form	Route Administr		Dose	Fre	equency	Therapy Duration	Indication(s)
TRIVIRIX 🗾		Sus	spect		QUID FANEOUS	Subcutan	eous			every 1 Day(s)	1.0 Day(s)	
Adverse Reaction Information	Term											
	Adve	rse Reac	tion Term(s)			Me	dDRA	Version			Reaction Duration	
Parotid gland enlargement					v.21	.1						

Canada Vigilance

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A 237 Report(s)

Summary of Reported	Adverse Reactions

Report Information	n	**AE	R = Adverse Re	action Rep	oort							
Adverse Reaction Report Number	ion Report Latest AER Version		Initial Receive	itial Received Date Latest Rece		ived Date	Source	of Report	Market Authorization Holder AER Number		Type of Report	Reporter Type
000060141	(0	1987-09-	14	1987-0	9-14		Other			Spontaneous	
Serious re	eport?			De	eath:		Disability:		y:	Congenital Anomaly:		
Yes			Lif	e Threater	ning:		Но	spitalizatio	n: Yes	Other Med	dically Important Co	onditions:
Patient Information	on											
Age	Gender		Height	W	eight	Report Outcome						
5 Years	Male			18 Ki	lograms	Unknown						
Link / Duplicate R	eport Infor	mation										
	Recor	d Type			Link AER** Number							
No duplicate or link	ked report.											
Product Informati	on											
Product Desci	ription	Health Pr	oduct Role	Dosage	Form	Route Administr		Dose	Fre	equency	Therapy Duration	Indication(s)
TRIVIRIX 📁	TRIVIRIX Suspect LIQU SUBCUTA			Subcutan	eous			every 1 Day(s)				
Adverse Reaction Information	Term											

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	

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Canada Vigilance
Summary of Reported Adverse Reactions

Report Informatio	n	**AE	R = Adverse R	eaction Re	port							
Adverse Reaction Report Number		R Version	Initial Receiv	tial Received Date Latest Recei		eived Date			Market Authorization Holder AER Number		Type of Report	Reporter Type
000060146		0	1987-09)-21	1987-0)9-21	F	lospital			Spontaneous	
	Serious report? Yes Life Threatening		Death: ening:					Congenital Anomaly: Other Medically Important Conditions:				
Patient Informatio	n											
Age	Gender		Height	V	Veight		Report	Outcome				
14 Months	Male					Not i	recover	ed/not resolve	ed			
Link / Duplicate R	eport Info	rmation										
·		d Type				Link AER** Number						
No duplicate or link	ed report.											
Product Informati	on											
Product Descr	ription	Health Pro	oduct Role	Dosag	e Form	Route Administr		Dose	Fr	equency	Therapy Duration	Indication(s)
TRIVIRIX 📃		Sus	spect		UID ANEOUS							
Adverse Reaction Information	Term											
	Adverse Reaction Term(s)					MedDRA Version					Reaction Duration	
Pyrexia							v.21.1					
Viral infection				v.21.1								

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

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237 Report(s)

Poport	Information
KEDUIL	IIIIOIIIIalloii

**AER = Adverse Reaction Report

Advers Reaction Ro Numbe	port	Latest AER Version Number	Initial Received Date	Latest Received Date		Market Authorization Holder AER Number	Type of Report	Reporter Type
0000601	17	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

i roddot iiii oi iii dtioii							
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	

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

Therapy Duration

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237 Report(s)

Indication(s)

Cammary of Reported Adverse i

Health Product Role

Suspect

Report Information	on **AE	R = Adverse Reacti	ion Report						
Adverse Reaction Report Number	Latest AER Version Number	Initial Received [Date Latest F	eceived Date	Source of Report	Autho	arket orization ER Number	Type of Report	Reporter Type
000060180	0	1986-12-31	19	36-12-31	Other			Spontaneous	
Serious re	eport?		Death:		Disabilit	ty:		Congenital	Anomaly:
Yes	;	Life T	hreatening:		Hospitalizatio	n: Yes	Other Med	dically Important C	onditions:
Patient Information	on								
Age	Gender	Height	Weight		Report Outcome				
14 Months	Female				Recovered/resolved				
Link / Duplicate R	Report Information								
	Record Type			Link AER	** Number				
No duplicate or linl	ked report.								
Product Informati	ion								

Adverse Reaction	Term
Information	

MMR II

Product Description

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	

Route of

Administration

Subcutaneous

Dose

Frequency

Dosage Form

LIQUID SUBCUTANEOUS

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

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Report Informat	ilo
Adverse Reaction Repo Number	rt
000060350	
Serious	r
Y	95
Patient Informa	tie
Age	
1 Years	
Link / Duplicate	F
No duplicate or li	in
Product Informa	at
Product Des	C
1 Todact Des	
MEGACILLIN	

**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
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 Informa	tion			
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	

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

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Summary of Reported	Adverse Reactions

Adverse Reaction Report Number	Latest AER Numl		Initial Rece	ived Date	Latest Rece	eived Date	Source	of Report	Autho	arket orization ER Number	Type of Report	Reporter Type
000060502	0		1987-0	4-29	1987-0)4-29	C	Other			Spontaneous	
Serious re	eport?				Death:			Disabilit	y:		Congenital	Anomaly:
Yes				Life Threat	ening:		Но	spitalizatio	n:	Other Med	dically Important Co	onditions:
Patient Information	on .											
Age	Gender		Height	V	Veight		Report (Outcome				
18 Months Female						Recovered/resolved						
Link / Duplicate R	eport Inforn	nation										
	Record	Туре			Link AER** Number							
No duplicate or line	ked report.											
Product Informati	on											
Product Desc	ription	Health Pr	oduct Role	Dosag	je Form	Route Administr	•	Dose	Fre	equency	Therapy Duration	Indication(s)
DIPHTHERIA TOX	OID	Conce	omitant		QUID TANEOUS	Subcutan	eous					
MMR II		Sus	spect		QUID FANEOUS					every 1 Day(s)		
SABIN		Conc	omitant	NOT SE	PECIFIED							

Adverse Reaction	ı erm
Information	

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

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

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237 Report(s)

	form	

**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
000060508	0	1 <mark>987</mark> -04-21	1987-04-21	Other		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome	
22 Months	Female			Recovered/resolved	

Link / Duplicate Report Information

Link AER Number Record Type**

No duplicate or linked report.

Product Information

1 Todact Illioilliation							
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	

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Canada Vigilance

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

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Summary of Reported Adverse Reactions

Report Informati	ion	**AE	R = Adverse R	eaction Re	eport							
Adverse Reaction Repor Number		ER Version mber	Initial Receiv	ved Date	Latest Rece	eived Date	Source	e of Report	Market Authorization Holder AER Numl		Type of Report	Reporter Type
000060510		0	1987-06	6-05	1987-0	06-05	(Other			Spontaneous	
Serious <mark>Y</mark> e	_		L	Death: Disability Life Threatening: Hospitalization			Congenital Anomaly: Other Medically Important Conditions:					
Patient Informat	ion											
Age	Gender		Height	V	Neight		Report	Outcome				
18 Months	Male						Unl	known				
Link / Duplicate	Report Info	rmation										
	Reco	rd Type				Link AER*	* Numb	er				
No duplicate or lir	nked report.											
Product Informa	tion									,		
Product Des	cription	Health Pr	oduct Role	Dosag	je Form	Route Administr		Dose	Fre	equency	Therapy Duration	Indication(s)
MMR II Su		spect	LIQUID SUBCUTANEOUS		Subcutan	eous						
Adverse Reaction	on Term											
Adverse Reaction Term(s)			Me	edDRA '	Version			Reaction Duration				
Seizure							v.21	.1				

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Canada Vigilance
Summary of Reported Adverse Reactions

Report Information	on	**AE	R = Adverse R	Reaction Re	eport							
Adverse Reaction Report Number		ER Version mber	Initial Recei	ved Date	Latest Rece	eived Date	Sourc	e of Report	Auth	larket orization AER Number	Type of Report	Reporter Type
000060514		0	1987-0	6-10	1987-0	06-10	Н	ospital			Spontaneous	
Serious r	eport?				Death:			Disabilit	y:		Congenital	Anomaly:
Yes	3		L	ife Threat	ening:		Н	ospitalizatio	n:	Other Med	dically Important Co	onditions:
Patient Information	on											
Age	Gender		Height	1	Veight		Report	Outcome				
3 Years	Female						Unl	known				
Link / Duplicate F	Report Info	rmation										
	Recor	d Type				Link AER*	* Numb	er				
No duplicate or lin	ked report.											
Product Informat	ion											
Product Desc	ription	Health Pr	oduct Role	Dosag	je Form	Route Administr		Dose	Fı	requency	Therapy Duration	Indication(s)
MMR II		Su	spect		QUID FANEOUS	Subcutan	eous					
Adverse Reaction Information	n Term											
Adverse Reaction Term(s)				MedDRA Version			Reaction Duration					
Decreased appetite					v.21							
Irritability							v.21					
Lymphadenopathy							v.21	.1				

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

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237 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
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

1 10 44 44 44 44 44 44 44 44 44 44 44 44 44							
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	

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

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Summary of Reported Adverse Reactions

Pain

Rhinitis

Salivary gland enlargement

Report Informati	on	**AE	R = Adverse R	eaction Re	eport							
Adverse Reaction Report Number		ER Version mber	n Initial Received Date Latest Receive		eived Date	Sourc	Source of Report Auth		arket orization ER Number	Type of Report	Reporter Type	
000060799		0	<mark>1987-</mark> 01	-16	1987-0)1-16		Other			Spontaneous	
Serious i	eport?				Death:			Disabilit	y:		Congenital	Anomaly:
Ye	s		Li	fe Threat	ening:		Н	lospitalizatio	n:	Other Me	dically Important Co	onditions:
Patient Informati	on											
Age	Gender		Height	V	Neight		Report	t Outcome				
5 Years	Male						Un	known	nown			
Link / Duplicate	Report Info	rmation										
	Reco	rd Type			Link AER** Number							
No duplicate or lin	ked report.											
Product Informa	tion									,		
Product Desc	ription	Health Pro	oduct Role	Dosag	je Form	Route Administr		Dose	Fre	equency	Therapy Duration	Indication(s)
MMR II		Sus	spect		QUID FANEOUS							
Adverse Reaction	n Term											
	Ad	verse Reac	tion Term(s)			MedDRA Version					Reaction Duration	
Lethargy				v.21.1								

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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Summary of Reported Adverse Reactions

Report Information	on **	AER = Adverse Reaction	n Report						
Adverse Reaction Report Number	Latest AER Versi Number	on Initial Received Da	ate Latest Rece	ived Date	Source of Report	Market Authorization Holder AER Number		Type of Report	Reporter Type
000061118	0	1987 -11-04	1-04 1987-1		1987-11-04 Other			Spontaneous	
Serious r	eport?		Death:		Disability:			Congenital	Anomaly:
Yes	5	Life The	reatening: Hospitalization: Yes		Other Med	lically Important C	onditions:		
Patient Informati	on								
Age	Gender	Height	Weight		Report Outcome				
12 Months	Female				Unknown				
Link / Duplicate I	Report Information								
	Record Type			Link AER*	* Number				
No duplicate or linked report.			_						
Product Informat	ion								

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			
		HOUID					

Product Description	Health Product Role	Dosage Form	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	

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Canada Vigilance
Summary of Reported Adverse Reactions

Report Information		**AEI	R = Adverse F	Reaction Re	eport							
Adverse Reaction Report Number	atest AER Numb		Initial Recei	ved Date	Latest Rece			Market Authorization Holder AER Number		Type of Report	Reporter Type	
000062897	0		1986-12-01 1986-12-			2-01	С	other			Spontaneous	Physician
Serious repo	ort?		Death: Life Threatening:		Disability: Hospitalization:				Congenital Anomaly: Other Medically Important Conditions:			
Patient Information												
Age	Gender		Height	\	Neight	Report Outcome						
9 Months 4	Female				Recovered/resolved							
Link / Duplicate Repo	ort Inform	ation										
	Record 7	Туре				Link AER*	* Numbe	r				
No duplicate or linked	report.											
Product Information	ı											
Product Descript	tion H	lealth Pro	oduct Role	Dosag	je Form	Route Administr		Dose	Fre	equency	Therapy Duration	Indication(s)
MMR II		Sus	Suspect LIQUID SUBCUTANEOUS									
Adverse Reaction Te Information	erm											
	Adver	rse Reac	tion Term(s)			MedDRA Version					Reaction Duration	
Rash maculo-papular						v.21.	1					

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Canada Vigilance
Summary of Reported Adverse Reactions

Report Informati	on	**AE	R = Adverse R	eaction Re	eport										
Adverse Reaction Report Number	Reaction Report Latest AER Version		Initial Receiv	ed Date	Latest Rece	ived Date	Source	e of Report	Market Authorization Holder AER Number		Type of Report	Reporter Type			
000067353 0			<mark>1988</mark> -01	-26	1988-0	1-26	(Other			Spontaneous				
Serious i	eport?			I	Death:			Disabilit	y:		Congenital Anomaly:				
Ye	S		L	ife Threat	ening:		Н	ospitalizatio	n:	Other Med	dically Important Co	onditions: Yes			
Patient Informati	on														
Age	Gender		Height	V	Veight		Report	Outcome							
14 Months	14 Months Female						Unk	nown							
Link / Duplicate	Report Info	rmation													
	Recor	d Type				Link AER*	* Numbe	er							
No duplicate or lin	ked report.														
Product Information	tion														
Product Desc	cription	Health Pr	oduct Role	Dosag	je Form	Route Administr		Dose	Fre	equency	Therapy Duration	Indication(s)			
TRIVIRIX =	TRIVIRIX Suspe				QUID FANEOUS										
Adverse Reactio Information	Adverse Reaction Term Information														
	Adverse Reaction Term(s)							/ersion			Reaction Duration				
<u>Parotitis</u>							v.21.	1							

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	Canada Vigilance
Summary	of Reported Adverse Reactions

Parotitis

Report Informati	on	**AE	R = Adverse F	Reaction Re	port								
Adverse Reaction Repor Number	r	Latest AER Version Number		Initial Received Date Latest Received Date Source of Report		Market Authorization Holder AER Number		Type of Report	Reporter Type				
000067355	355 0		1988-0	1-26	1988-0	1-26		Other			Spontaneous		
Serious	report?				Death:			Disabilit	y:		Congenital Anomaly:		
Ye	s		L	ife Threate	ening:		Но	spitalizatio	n:	Other Med	dically Important Co	onditions: Yes	
Patient Informat	ion												
Age	Gender		Height Weight				Report	rt Outcome					
13 Months	Male						Unk	nown					
Link / Duplicate	Report Info	rmation											
	Recor	d Type				Link AER*	* Numbe	er					
No duplicate or lir	nked report.												
Product Informa	tion												
Product Description He		Health Pr	oduct Role	Dosag	e Form	Route Administr		Dose	Freq	uency	Therapy Duration	Indication(s)	
TRIVIRIX	Suspect SL			UID ANEOUS									
Adverse Reaction	n Term												
	Ad	verse Reac	tion Term(s)			Me	MedDRA Version Reaction Duration						

v.21.1

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

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Report Information	on	**AE	R = Adverse Re	eaction Re	eport									
Adverse Reaction Report Number	Reaction Report Latest AER Version		Initial Receiv	ed Date	Latest Rece	ived Date	Source	e of Report	Market Authorization Holder AER Number		Type of Report	Reporter Type		
000067356 0			1 <mark>988</mark> -01	-26	1988-0	1-26	(Other			Spontaneous			
Serious r	eport?			I	Death:			Disabilit	y:		Congenital	Congenital Anomaly:		
Yes	3		Li	fe Threat	ening:		H	ospitalizatio	n:	Other Med	lically Important Co	onditions: Yes		
Patient Information	on													
Age	Gender		Height	V	Veight		Report	Outcome						
14 Months	14 Months						Unl	known						
Link / Duplicate F	Report Info	rmation												
	Recor	d Type				Link AER*	* Numb	er						
No duplicate or lin	ked report.													
Product Informat	ion													
Product Desc	ription	Health Pr	oduct Role	Dosag	je Form	Route Administr		Dose	Fre	equency	Therapy Duration	Indication(s)		
TRIVIRIX	TRIVIRIX Suspect		spect	LIC SUBCUT	QUID FANEOUS									
Adverse Reaction Information	n Term													
	Adverse Reaction Term(s)						edDRA	Version			Reaction Duration			
Parotitis							v.21	.1						

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

Report Information	n	**AE	R = Adverse F	Reaction Re	eport							
Adverse Reaction Report Number		t AER Version Number Initial Received			Latest Rece	eived Date	Sourc	ce of Report Author		arket orization AER Number	Type of Report	Reporter Type
000067357	0		1 <mark>988</mark> -0	1-26	1988-0	1-26	Other				Spontaneous	
Serious re	eport?			l	Death:			Disabilit	y:		Congenital	Anomaly:
Yes			L	ife Threat	ening:		Н	ospitalizatio	n:	Other Med	dically Important Co	onditions: Yes
Patient Information	on .											
Age	Gender		Height	V	Neight		Report	Outcome				
14 Months	Male						Un	known				
Link / Duplicate R	eport Inform	ation										
	Record 7	Гуре				Link AER*	* Numb	er				
No duplicate or link	ked report.											
Product Informati	on											
Product Descr	Product Description Health Product Role				ge Form	Route Administr		Dose	Fre	equency	Therapy Duration	Indication(s)
TRIVIRIX 📃		Sus	Suspect LIQUID SUBCUTANEOUS									
Adverse Reaction Information	Term											
	Adverse Reaction Term(s)							Version			Reaction Duration	
Parotitis							v.21	.1				

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Canada Vigilance
Summary of Reported Adverse Reactions

Report Informatio	n	**AE	R = Adverse R	Reaction Re	eport										
Adverse Reaction Report Number		R Version	Initial Recei	ved Date	Latest Rece	eived Date				arket orization ER Number	Type of Report	Reporter	Туре		
000067358		0	1988- 0 ²	1-26	1988-0)1-26		Other			Spontaneous				
Serious re	Serious report?			Death:				Disabilit	y:		Congenital	Anomaly:			
Yes			Life Threatening:				Но	spitalizatio	n:	Other Med	dically Important Co	onditions:	Yes		
Patient Information	on														
Age	Gender		Height	V	Veight		Report	Outcome							
20 Months	Male					Unknown									
Link / Duplicate R	eport Info	rmation													
	Recor	d Type				Link AER*	* Numbe	er							
No duplicate or link	ked report.														
Product Informati	on														
Product Descr	ription	Health Pro	oduct Role	Dosag	je Form	Route Administr		Dose	Fre	equency	Therapy Duration	Indication	on(s)		
TRIVIRIX 📁		Sus	spect		QUID FANEOUS										
Adverse Reaction Information	Term														
	Adverse Reaction Term(s)					Me	edDRA V	ersion			Reaction Duration				
Parotitis	rotitis							v.21.1							

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

Report Information		**AEI	R = Adverse Re	action Re	eport							
Adverse Reaction Report Number	Latest AER Numbe		Initial Received Date Latest Re			eived Date	ed Date Source of Report Author			arket orization ER Number	Type of Report	Reporter Type
000067359	0		1988-01	26	1988-01-26 Other						Spontaneous	
Serious rep	Serious report?			ı	Death:			Disabilit	y:		Congenital	Anomaly:
Yes			Lit	e Threat	ening:	Hospitalization:				Other Me	dically Important Co	onditions: Yes
Patient Information	<u> </u>											
Age	Gender		Height	V	Neight		Report	Outcome				
15 Months	Male						Unl	known				
Link / Duplicate Re	port Informa	ation										
	Record T	уре				Link AER*	* Numb	er				
No duplicate or linke	d report.											
Product Informatio	n											,
Product Descrip	ption H	ealth Pro	oduct Role	Dosag	je Form	Route Administr		Dose	Fre	equency	Therapy Duration	Indication(s)
TRIVIRIX =		Sus	spect		QUID FANEOUS							
Adverse Reaction Information	Term											
	Adver	se React	tion Term(s)			MedDRA Version					Reaction Duration	
Parotitis	arotitis						v.21.1					

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

Report Information		**AEF	R = Adverse F	eaction R	eport								
Adverse Reaction Report Number	atest AER \ Numbe		Initial Recei	ved Date	Latest Rece	eived Date	Sourc	Source of Report Author Holder AE			Type of Report	Reporter Type	
000067360	0		1988-01-26 1988					Other	Spontaneous				
Serious repo	Serious report? Death:							Disabilit	:y:		Congenital	Anomaly:	
Yes	ife Threat	tening:		Н	ospitalizatio	n:	Other Me	dically Important Co	onditions: Yes				
Patient Information													
Age	Gender		Height	,	Weight		Report	Outcome					
15 Months	Female					Unknown							
Link / Duplicate Rep	oort Informa	ation											
	Record T	уре				Link AER*	* Numb	er					
No duplicate or linked	d report.												
Product Information	1												
Product Descrip	otion H	ealth Pro	oduct Role	Dosa	ge Form	Route Administr		Dose	Fr	equency	Therapy Duration	Indication(s)	
TRIVIRIX 📁	TRIVIRIX Suspect SUBCUTANEOUS												
Adverse Reaction T	erm												
	Adverse Reaction Term(s)							Version			Reaction Duration		
Parotitis	arotitis arotitis							.1					

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

Reaction Duration

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Adverse Reaction Report Number		R Version	Initial Recei	ved Date	Latest Rece	eived Date	Source	of Report	Auth	larket orization AER Number	Type of Report	Reporter Type
000067361		0	1988-01	1-26	1988-01-26			Other			Spontaneous	
Serious re				Disabilit	y:	Congenital Anomaly:						
Yes	Yes			ife Threat	ening:		Н	spitalizatio	n:	Other Med	dically Important Co	onditions: Yes
Patient Informatio	n											
Age	Gender		Height Weigh				Report	Outcome				
15 Months	Female					Unknown						
Link / Duplicate R	eport Info	rmation										
	Recor	d Type			Link AER** Number							
No duplicate or link	ed report.											
Product Information	on											
Product Descr	Product Description Health Produ		roduct Role	Dosag	je Form	Route Administr		Dose	Fr	requency	Therapy Duration	Indication(s)
TRIVIRIX 📮		Su	spect		QUID FANEOUS							

MedDRA Version

v.21.1

Information

Parotitis

Adverse Reaction Term(s)

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

Canada Vigilance
Summary of Reported Adverse Reactions

Report Information	on	**AE	R = Adverse R	eaction Re	port								
Adverse Reaction Report Number		ER Version mber	Initial Recei	ved Date	Latest Rece	eived Date	Source	of Report	Market Authorization Holder AER Number		Type of Report	Reporter 1	Гуре
000067362		0	1988- 0 ²	1-26	1988-0	1-26	0	ther		Spontaneous			
Serious report?			Death:					Disabilit	y:	Congenital Anomaly:			
Yes			L	ife Threat	ening:		Hos	spitalizatio	n:	Other Med	dically Important Co	onditions:	Yes
Patient Information	atient Information												
Age	Gender		Height	V	Veight		Report C	Outcome					
18 Months							Unkn	nown					
Link / Duplicate R	Report Info	rmation											
	Recor	d Type				Link AER*	* Numbe	r					
No duplicate or linl	ked report.												
Product Informat	ion												
Product Desc	ription	Health Pr	oduct Role	Dosag	e Form	Route Administr		Dose	Fre	quency	Therapy Duration	Indicatio	n(s)
TRIVIRIX		Sus	spect		UID ANEOUS								
Adverse Reaction Information	n Term												
	Adverse Reaction Term(s)						MedDRA Version				Reaction Duration		
Parotitis	Parotitis						v.21.1						

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Report Informatio	n	**AE	R = Adverse F	Reaction Re	eport								
Adverse Reaction Report Number	Latest AER Numb		Initial Rece	ived Date	Date Latest Received		Sourc	e of Report	Autho	arket orization ER Number	Type of Report	Reporter	Туре
000067363	0		1988-0	1-26	1988-01-26			Other			Spontaneous		
Serious report?							Disabilit	y:		Congenital	Anomaly:		
Yes			Life Threatening:				Н	ospitalizatio	n:	Other Med	dically Important Co	onditions:	Yes
Patient Informatio	n												
	Age Gender Height						Report	Outcome					
1 Years					Weight		-	known					
Link / Duplicate R	eport Inform	ation											
•	Record 1				Link AER** Number								
No duplicate or link	ed report.												
Product Information	on												
Product Descr	iption H	lealth Pr	oduct Role	Dosag	je Form	Route Administr		Dose	Fre	equency	Therapy Duration	Indicati	on(s)
TRIVIRIX 📮	Suspect S				QUID FANEOUS								
Adverse Reaction Information	Term												
	Adverse Reaction Term(s)						dDRA	Version			Reaction Duration		

Parotitis

v.21.1

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

Report Information	on	**AE	R = Adverse R	eaction Re	eport								
Adverse Reaction Report Number		ER Version mber	Initial Recei	ved Date	Latest Received Date Source of Repo				Autho	arket orization ER Number	Type of Report	Reporter	Туре
000067364		0	<mark>1988</mark> -01	1-26	1988-0)1-26	-26 Other Spontaneous						
Serious report?					Death:			Disabilit	y:		Congenital	Anomaly:	,
Yes			L	ife Threat	ening:		Но	spitalizatio	n:	Other Med	dically Important Co	onditions:	Yes
Patient Information	on												
Age	Gender		Height	V	Neight		Report (Outcome					
13 Months							Unk	nown					
Link / Duplicate F	Report Info	rmation											
	Recor	d Type				Link AER*	* Numbe	r					
No duplicate or lin	ked report.												
Product Informat	ion												
Product Desc	ription	Health Pr	oduct Role	Dosag	je Form	Route Administr		Dose	Fre	equency	Therapy Duration	Indication	on(s)
TRIVIRIX					QUID FANEOUS								
Adverse Reaction Information	Adverse Reaction Term Information												
	Ad	verse Reac	tion Term(s)			Me	edDRA V	ersion er			Reaction Duration		
Parotitis	rotitis						v.21.1						

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

237 Report(s)

Report Information **AER = Adverse Reaction Report Market Adverse Latest AER Version **Reaction Report Initial Received Date Latest Received Date Source of Report** Authorization Type of Report **Reporter Type** Number Number **Holder AER Number** 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** Height Weight **Report Outcome** Age Gender 14 Months Male Unknown **Link / Duplicate Report Information Record Type Link AER** Number** No duplicate or linked report. Product Information Route of **Product Description Health Product Role Dosage Form Frequency Therapy Duration** Indication(s) Dose Administration LIQUID **TRIVIRIX** Suspect SUBCUTANEOUS

Information			
Advers	se Reaction Term(s)	MedDRA Version	Reaction Duration
Parotitis		v.21.1	

Adverse Reaction Term

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Canada Vigilance
Summary of Reported Adverse Reactions

Report Information	on	**AE	R = Adverse R	eaction Re	eport							
Adverse Reaction Report Number		ER Version mber	Initial Recei	ved Date	Latest Received Date Source of Report			Autho	rket rization ER Number	Type of Report	Reporter Type	
000067366	0067366 0 1988-01-26 19				1988-0	1-26	Ot	ther			Spontaneous	
Serious report?					Death:			Disability:			Congenital	Anomaly:
Yes			L	ife Threat	ening:		Hos	spitalizatio	n:	Other Med	dically Important Co	onditions: Yes
Patient Informati	on											
Age	Gender		Height	V	Neight		Report O	utcome				
14 Months							Unkn	own				
Link / Duplicate I	Report Info	rmation										
	Recor	d Type				Link AER*	* Number					
No duplicate or lin	ked report.											
Product Informat	ion											
Product Desc	ription	Health Pr	oduct Role	Dosag	je Form	Route Administr		Dose	Fre	quency	Therapy Duration	Indication(s)
TRIVIRIX					QUID FANEOUS							
Adverse Reactio Information	Adverse Reaction Term Information											
	Adverse Reaction Term(s)					Me	edDRA Ve	ersion			Reaction Duration	
Parotitis	Parotitis					v.21.1						

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

Canada Vigilance
Summary of Reported Adverse Reactions

Report Informati	on	R = Adverse R	eaction Re	port									
Adverse Reaction Repor Number	T I	ER Version mber	Initial Recei	Received Date Latest Receive		eived Date			Market Authorization Holder AER Number		Type of Report	Reporter	Туре
000067367		0	1988-01-26 1988-01-			1-26		Other			Spontaneous		
Serious	report?			ı	Death:			Disabilit	y:		Congenital	Anomaly:	
Ye	S		L	ife Threat	ening:		Н	ospitalizatio	n:	Other Med	dically Important Co	onditions:	Yes
Patient Informat	ion												
Age	Gender		Height	V	Veight		Report	Outcome					
14 Months	Male						Un	known					
Link / Duplicate	Report Info	rmation											
	Recoi	rd Type				Link AER*	* Numb	er					
No duplicate or lir	nked report.												
Product Informa	tion												
Product Desc	cription	Health Pr	oduct Role	Dosag	e Form	Route Administr		Dose	Fre	equency	Therapy Duration	Indication	on(s)
TRIVIRIX 📁		Sus	spect	LIC SUBCUT	UID ANEOUS								
Adverse Reaction	n Term					_							
	Ad	verse Reac	tion Term(s)			Me	dDRA	Version			Reaction Duration		
Parotitis							v.21	.1					

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

Report Information	n	**AE	R = Adverse R	eaction Re	eport							
Adverse Reaction Report Number	Latest AER Num		Initial Recei	ved Date	Latest Rece	eived Date	Source of Report Auth		Autho	arket orization ER Number	Type of Report	Reporter Type
000067368	0		<mark>1988</mark> -0	1-26	1988-0)1-26		Other			Spontaneous	
Serious re	port?				Death:			Disabilit	y:		Congenital	Anomaly:
Yes			L	ife Threat	ening:		Н	ospitalizatio	n:	Other Me	dically Important Co	onditions: Yes
Patient Informatio	n											
Age	Gender		Height	V	Veight		Report	Outcome				
13 Months	Male						Un	known				
Link / Duplicate Re	eport Inforr	nation										
	Record	Туре				Link AER*	* Numb	er				
No duplicate or link	ed report.											
Product Information	on											1
Product Descri	iption	Health Pr	oduct Role	Dosag	je Form	Route Administr		Dose	Fre	equency	Therapy Duration	Indication(s)
TRIVIRIX		Sus	spect		QUID ANEOUS							
Adverse Reaction Information	Term											
	Adve	erse Reac	tion Term(s)			Me	dDRA	Version			Reaction Duration	
Parotitis							v.21	.1				

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

Canada Vigilance
Summary of Reported Adverse Reactions

Report Information	on	**AE	R = Adverse F	Reaction Re	eport							
Adverse Reaction Report Number		ER Version mber	Initial Rece	ived Date	ved Date Latest Receive				Marke Authoriza Holder AER I	tion	Type of Report	Reporter Type
000067370		0	1988-0	1-26	1988-0	1-26	Oth	er			Spontaneous	
Serious r	eport?			l	Death:			Disabilit	y:	Congenital Anomaly:		
Yes	5		l	_ife Threat	ening:		Hosp	italizatio	n: O	ther Med	dically Important Co	onditions: Yes
Patient Information	on											
Age	Gender		Height	V	Veight		Report Ou	tcome				
14 Months	Female						Unkno	wn				
Link / Duplicate F	Report Info	rmation										
	Recor	d Type				Link AER*	* Number					
No duplicate or lin	ked report.											
Product Informat	ion											
Product Desc	ription	Health Pr	oduct Role	Dosag	je Form	Route Administr		Dose	Freque	ency	Therapy Duration	Indication(s)
MEASLES MUMP RUBELLA VIRUS		Sus	spect		QUID FANEOUS							
Adverse Reaction Information	n Term											
	Ad	verse Reac	tion Term(s)			Me	edDRA Ver	sion			Reaction Duration	
Parotitis							v.21.1					

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

Report Information	on	**AE	R = Adverse R	eaction Re	eport								
Adverse Reaction Report Number	Latest AEF Num		Initial Recei	ved Date	red Date Latest Recei				Market Authorization Holder AER Number		Type of Report	Reporter	Туре
000067372	0		1988- 01	-26	1988-0	1-26		Other			Spontaneous		
Serious r	eport?				Death:			Disabilit	y:		Congenital	Anomaly:	
Yes	S		L	ife Threat	ening:		Н	ospitalizatio	n:	Other Me	dically Important Co	onditions:	Yes
Patient Informati	on												
Age	Gender		Height	V	Neight		Report	Outcome					
15 Months	Male						Unl	known					
Link / Duplicate I	Report Inforr	mation											
	Record	Туре				Link AER*	* Numb	er					
No duplicate or lin	ked report.												
Product Informat	tion											_	
Product Desc	ription	Health Pr	oduct Role	Dosag	ge Form	Route Administr		Dose	Fre	equency	Therapy Duration	Indicati	on(s)
TRIVIRIX		Sus	spect		QUID FANEOUS								
Adverse Reactio Information	n Term					_							
	Adve	erse Reac	tion Term(s)			Me	dDRA	Version			Reaction Duration		
Parotitis							v.21	.1					

Canada Vigilanaa

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

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Canada vigilance	
Summary of Reported Adverse Reactions	•

Report Information	on	**AE	R = Adverse F	Reaction Re	port							
Adverse Reaction Report Number	Reaction Report Latest AER Version		Initial Recei	ved Date	Date Latest Received Date		Source	e of Report	Autho	arket orization ER Number	Type of Report	Reporter Type
000103355	(0	1970-0	1-26	1970-0	1-26	Н	ospital			Spontaneous	
Serious r	eport?			ı	Death:			Disabilit	y:		Congenital	Anomaly:
Yes	3		L	ife Threat	ening:		H	ospitalizatio	n:	Other Med	dically Important Co	onditions:
Patient Information	on											
Age	Gender		Height	V	Veight		Report	Outcome				
16 Months	Female			13 k	13 Kilograms			Unknown				
Link / Duplicate F	Report Infor	mation										
	Record	d Type			Link AER** Number							
No duplicate or lin	ked report.											
Product Informat	ion											
Product Desc	ription	Health Pr	oduct Role	Dosag	e Form	Route Administr		Dose	Fre	equency	Therapy Duration	Indication(s)
ATTENUVAX		Sus	spect	NOT SP	ECIFIED	Parente	ral	0.5 mL				
Adverse Reaction Information	n Term											
	Adv	erse Reac	tion Term(s)			Ме	dDRA	Version			Reaction Duration	

v.21.1 v.21.1

v.21.1

Irritability

Irritability Pyrexia

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

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		
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	tion					
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 Vigilanaa

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

Canada vigilance	
Summary of Reported Adverse Re	eactions

Adverse Reaction Report Number			n Initial Received Date		Latest Received Date		Source	e of Report	Market Authorization Holder AER Number		Type of Report	Reporter Type
000103437	0		1970-0	3-09	1970-0	3-09	Н	ospital			Spontaneous	
Serious r	eport?				Death:			Disabilit	y:		Congenital	Anomaly:
Yes	3		L	ife Threat	ening:		Нс	spitalizatio	n:	Other Med	dically Important Co	onditions:
Patient Information	on											
Age	Gender		Height	V	Weight	Report Outcome						
3 Years	Male					Unknown						
Link / Duplicate R	Report Inforn	nation										
	Record	Туре			Link AER** Number							
No duplicate or line	ked report.											
Product Informat	ion											
Product Description He		Health P	roduct Role	Dosag	je Form	Route Administr		Dose	Fre	equency	Therapy Duration	Indication(s)
RUBEOVAX Suspect POWDER FOR SOLUTION SUBCUTANEOUS							1.0 Day(s)					
Adverse Reaction Information	n Term		·				•					

Adverse Reaction Term(s)	INIEGURA VERSION	Reaction Duration
Pallor	v.21.1	
Pyrexia	v.21.1	
Rash	v.21.1	

Canada Vigilanco

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

S	Summary of Reported Adverse Reactions

Rash erythematous

Report Informatio	n	**AE	R = Adverse R	eaction Re	eport							
Adverse Reaction Report Number	tion Report Latest AER Version Initial Received Date Latest Received		eived Date	Sourc	e of Report	Auth	larket orization AER Number	Type of Report	Reporter Type			
000103439	0	1	1 <mark>970</mark> -03	3-09	1970-0	03-09	F	lospital			Spontaneous	
Serious report? Yes			L		Death: Disability: Threatening: Hospitalization:				Congenital Anomaly: Other Medically Important Conditions:			
Patient Informatio	n											
Age	Gender		Height	V	Veight		Report	Outcome				
20 Months	Male					F	Recover	ed/resolved				
Link / Duplicate R	eport Infori	mation										
	Record	Туре				Link AER*	* Numb	er				
No duplicate or link	ed report.											
Product Information	on											,
Product Descr	ription	Health Pr	oduct Role	Dosag	je Form	Route Administr		Dose	Fr	equency	Therapy Duration	Indication(s)
RUBEOVAX Suspect POWDER FOR SOLUTION SUBCUTANEOUS							1.0 Day(s)					
Adverse Reaction Information	Term											
	Adv	erse Reac	tion Term(s)			MedDRA Version					Reaction Duration	
Pyrexia	Pyrexia					v.21	.1					

v.21.1

Report Runtime: Initial Received Date: Latest Received Date: 2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Latest Received Date: Total Number of Reports:

Report Informat	tion				
Adverse Reaction Report Number					
000103528					
Serious report?					
Yo	Yes				
Patient Information					
Age Ge					
18 Months	Ма				
Link / Dunlingto Bonort I					

Report Informatio	**AE	R = Adverse Reaction Re	eport				
Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date		Market Authorization Holder AER Number	Type of Report	Reporter Type
000103528	0	197 <mark>0-03-25</mark>	1970-03-25	Hospital		Spontaneous	

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

Patient Informa	tion			
Age	Gender	Height	Weight	Report Outcome
18 Months	Male			Unknown

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

Dun dunat	Infama - 1! - 11
Product	Information

i roddot iirioriiidtioii							
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	

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

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Report Information	on	**AE	R = Adverse R	eaction Re	eport								
Adverse Reaction Report Number		R Version nber			Latest Received Date		Sourc	e of Report	Market Authorization Holder AER Number		Type of Report	Reporter Type	
000103606)	<mark>1970</mark> -0 ²	1-16	1970-0	14-16	Н	ospital			Spontaneous		
Serious r				Death:			Disabilit	y:	Congenital Anomaly:				
Yes			L	ife Threate	ening:	Hospitalization:				Other Medically Important Conditions:			
Patient Information	on												
Age	Gender		Height	V	Veight		Report	Outcome					
18 Months	Male						Unl	known					
Link / Duplicate F	Report Infor	mation											
	Record	d Type			Link AER** Number								
No duplicate or lin	ked report.												
Product Informat	ion												
Product Desc	ription	Health Pr	oduct Role	Dosag	e Form	Route Administr		Dose	Fre	equency	Therapy Duration	Indication(s)	
RUBEOVAX 📮		Sus	spect	SOLU	ER FOR JTION ANEOUS								
Adverse Reaction Information	n Term					_							
Adverse Reaction Term(s)						Me	dDRA	Version		Reaction Duration			

v.21.1

v.21.1

Injection site mass

Pyrexia

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Report Information	**AER = Adverse Reaction Report												
Adverse Reaction Report Number	Latest AEI Num				Latest Received Date		Source	of Report	Market Authorization Holder AER Number		Type of Report	Reporter Type	
000103609	0)	1970-0	4-17	1970-0)4-17	Н	ospital			Spontaneous		
Serious report?				Į.	Death: Di			Disabilit	y:	Anomaly:			
Yes			L	ife Threat	e Threatening: Hospitalization:					Other Medically Important Conditions:			
Patient Information	on												
Age	Gender		Height	V	Weight Report Outcome								
5 Years	Female							Jnknown					
Link / Duplicate F	Report Infor	mation											
	Record	І Туре			Link AER** Number								
No duplicate or lin	ked report.												
Product Informat	ion												
Product Desc	ription	Health Pr	oduct Role	Dosag	e Form	Route Administr		Dose	Fre	equency	Therapy Duration	Indication(s)	
MEASLES VACCI	SLES VACCINE 🔼 Suspect		SOLU	OWDER FOR SOLUTION CUTANEOUS			0.5 mL			1.0 Day(s)			
Adverse Reaction	n Term												

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

Information

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Canada Vigilance								
Summary of Reported Adverse Reactions								

Report Information	eport												
Adverse Reaction Report Number Latest AER Version Number			Initial Received Date Latest Rec		Latest Rece	eived Date Sourc		e of Report	Market Authorization Holder AER Number		Type of Report	Reporter Type	
000103832		0	1 <mark>970</mark> -06	1970-0	6-08	Н	ospital			Spontaneous			
Serious r		[Death:			Disabilit	y:		Congenital	Anomaly:			
Yes	3		L	ife Threate	ening:		H	ospitalizatio	n:	Other Med	dically Important Co	onditions:	
Patient Information	on												
Age	Gender		Height	V	Veight		Report	Outcome					
4 Years	Male						Recovered/resolved						
Link / Duplicate F	Report Info	mation											
	Recor	d Type				Link AER*	* Numb	er					
No duplicate or lin	ked report.												
Product Informat	ion												
Product Desc	ription	Health Pro	oduct Role	Dosag	e Form	Route Administr		Dose	Fre	equency	Therapy Duration	Indication(s)	
RUBEOVAX	X 📃 Suspect		SOLU	ER FOR JTION ANEOUS									
Adverse Reaction Information	n Term					,							
Adverse Reaction Term(s)						MedDRA Version Reaction Duration							

v.21.1 v.21.1

Lymphadenopathy

Pyrexia

Canada Vigilanaa

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Canada vigilance
Summary of Reported Adverse Reactions

**AER = Adverse Reaction Report												
Adverse Reaction Report Number		R Version nber				eived Date	Sourc	e of Report	Autho	arket orization ER Number	Type of Report	Reporter Type
000103833	()	1970-06	6-09	1970-0	6-09	Н	lospital			Spontaneous	
Serious r	[Death:			Disabilit	y:		Congenital	Anomaly:			
Yes	3		L	ife Threate	ening:		Н	ospitalizatio	n: Yes	Other Med	dically Important Co	onditions:
Patient Information	on											
Age	Gender		Height	V	Veight		Report	Outcome				
3 Years	Female						Unl	known				
Link / Duplicate F	Report Infor	mation										
	Record	d Type				Link AER*	* Numb	er				
No duplicate or lin	ked report.											
Product Informat	ion											
Product Desc	ription	Health Pro	oduct Role	Dosag	e Form	Route Administr		Dose	Fre	equency	Therapy Duration	Indication(s)
RUBEOVAX	=	Sus	spect	SOLU	ER FOR JTION ANEOUS							
Adverse Reaction Information	n Term											
	Adv	erse React	tion Term(s)			Me	edDRA	Version			Reaction Duration	_

v.21.1 v.21.1

Delirium

Hyperpyrexia

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

Report Informatio	n	**AE	R = Adverse F	Reaction Re	eport							
Adverse Reaction Report Number		R Version nber	Initial Received D		e Latest Received Date		Source	e of Report	Market Authorization Holder AER Number		Type of Report	Reporter Type
000104019		0	1 <mark>970</mark> -0	2-16	1970-0)2-16					Spontaneous	Physician
Serious report?				Death:				Disabilit	y:		Congenital	Anomaly:
Yes			L	ife Threat	ening:		Н	ospitalizatio	n:	Other Med	dically Important C	onditions:
Patient Information	n											
Age	Gender		Height	1	Weight Report Outcome							
2 Years	Female			10	10 Kilograms Unknown							
Link / Duplicate R	eport Infor	mation										
	Record	d Type			Link AER** Number							
No duplicate or link	ed report.											
Product Informati	on											
Product Descr	ription	Health Pr	oduct Role	Dosag	ge Form	Route Administr		Dose	Fr	equency	Therapy Duration	Indication(s)
LIRUGEN 📮		Sus	spect	POWDER FOR SOLUTION SUBCUTANEOUS		Subcutan	eous	0.5 mL			1.0 Day(s)	
Adverse Reaction	Term											

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

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

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237 Report(s)

Summary of Reported Adverse Reactions

Febrile convulsion

Pyrexia

Report Information	on	**AE	R = Adverse Re	action Re	port							
Adverse Reaction Report Number		R Version	Initial Receive	ed Date	Latest Rece	eived Date	Sourc	e of Report	Autho	arket orization ER Number	Type of Report	Reporter Type
000104073		0	1970-04-	29	1970-0	14-29					Spontaneous	Physician
Serious r	eport?			[Death:			Disabilit	y:		Congenital	Anomaly:
Yes	3		Lif	e Threate	ening:		Н	ospitalizatio	n:	Other Med	dically Important Co	onditions:
Patient Information	on											
Age	Gender		Height	V	Veight		Report	Outcome				
17 Months	Male						Un	known				
Link / Duplicate F	Report Info	rmation										
	Recor	d Type				Link AER*	* Numb	er				
No duplicate or lin	ked report.											
Product Informat	ion											,
Product Desc	ription	Health Pro	oduct Role	Dosag	e Form	Route Administr		Dose	Fre	equency	Therapy Duration	Indication(s)
LIRUGEN		Sus	spect	SOLU	ER FOR JTION ANEOUS							
Adverse Reaction Information	n Term											
	Adv	erse Reac	tion Term(s)			Me	dDRA	Version			Reaction Duration	

v.21.1 v.21.1

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

Report Information	n **	AER = Adverse Read	tion Re	eport						
Adverse Reaction Report Number	Latest AER Versi Number	Initial Received	Date	Latest Rece	ived Date			arket orization ER Number	Type of Report	Reporter Type
000104538	0	<mark>1970</mark> -09-16	5	1970-09	9-16	Hospital			Spontaneous	
Serious re	Serious report? Death: Disability:				y:		Congenital	Anomaly:		
Yes		Life Threatening: Hospitalization: Yes Other Medically Important Condition				onditions:				
Patient Information	on									
Age	Gender	Height	٧	Veight		Report Outcome				
18 Months	Male					Unknown				
Link / Duplicate R	eport Information									
Record Type Link AER** Number										
No duplicate or link	ked report.	<u> </u>				<u> </u>				

Pr	oduct Information							
	Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
M	EASLES VACCINE)	Suspect	POWDER FOR SOLUTION SUBCUTANEOUS					

Adverse Reaction Term	1
Information	

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A 237 Report(s)

Canada Vigilance
Summary of Reported Adverse Reactions

Report Informati	on	**AE	R = Adverse F	Reaction Re	eport							
Adverse Reaction Report Number	Latest AER		Initial Recei	ved Date	Latest Reco	eived Date	Source	of Report	Auth	Market orization AER Number	Type of Report	Reporter Type
000104981	0		1970-0	1-14	1970-0	01-14	Но	ospital			Spontaneous	
Serious i	report?				Death:			Disabilit	y:		Congenital	Anomaly:
Ye	s		L	ife Threat	ening:		Нс	spitalizatio	n:	Other Med	dically Important Co	onditions:
Patient Informati	on											
Age	Gender		Height	V	Neight		Report	Outcome				
29 Months	Female					F	Recovere	d/resolved				
Link / Duplicate	Report Inforn	nation										
	Record	Туре		Link AER** Number								
No duplicate or lin	ked report.											
Product Information	tion											_
Product Desc	cription	Health Pr	oduct Role	Dosag	je Form	Route Administr		Dose	Fı	requency	Therapy Duration	Indication(s)
LIRUGEN		Sus	spect	SOLI	ER FOR JTION TANEOUS						1.0 Day(s)	
Adverse Reactio Information	n Term											
	Adve	erse Reac	tion Term(s)			Me	edDRA V	ersion			Reaction Duration	
Pyrexia							v.21.	1				

Canada Vigilanaa

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Canada vigilance	
Summary of Reported Adverse React	ions

Report Informatio	n	**AE	R = Adverse R	eaction Re	port							
Adverse Reaction Report Number	Latest AER Numl		Initial Recei	ved Date	Latest Rece	eived Date	Source	e of Report	of Report Author Holder A		Type of Report	Reporter Type
000105254	0		<mark>1970</mark> -10)-07	1970-1	0-07	Н	ospital			Spontaneous	
Serious re	eport?				Death:			Disabilit	y:		Congenital	Anomaly:
Yes			L	ife Threat	ening:		Н	ospitalizatio	n:	Other Med	dically Important Co	onditions:
Patient Informatio	n											
Age	Gender		Height	V	Veight	Report Outcome						
5 Years	Female			18 l	Kilograms	F	Recover	ed/resolved				
Link / Duplicate R	eport Inforn	nation										
	Record	Туре			Link AER** Number							
No duplicate or link	ced report.											
Product Informati	on											
Product Descr	ription	Health Pr	oduct Role	Dosag	osage Form Route of Administration Dose				Fr	equency	Therapy Duration	Indication(s)
MERUVAX =		Sus	spect	SOLU	ER FOR JTION ANEOUS	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 Vigilanco

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

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237 Report(s)

Summary of Reported Adverse Reactions

Body temperature increased

Seizure

Report Information	on	**AE	R = Adverse R	eaction Re	eport							
Adverse Reaction Report Number	Latest AEF Num		rsion Initial Received Date Latest Received			ived Date	Sourc	e of Report	Autho	arket orization ER Number	Type of Report	Reporter Type
000105296	0		<mark>1970</mark> -10	-15	1970-1	0-15	Н	ospital			Spontaneous	
Serious re	eport?				Death:		Disability:			Congenital Anomaly:		
Yes	3		Li	fe Threat	ening:		Н	ospitalizatio	n: Yes	Other Medically Important Conditions:		
Patient Information	on											
Age	Gender		Height	V	Veight		Report	Outcome				
21 Months	Male					Unknown						
Link / Duplicate R	Report Inform	mation										
	Record	Туре				Link AER*	* Numb	er				
No duplicate or linl	ked report.											
Product Informati	ion											
Product Desc	ription	Health Pr	oduct Role	Dosag	je Form	Route Administr		Dose	Fre	equency	Therapy Duration	Indication(s)
LIRUGEN =		Sus	spect	SOLI	ER FOR JTION ANEOUS							
Adverse Reaction Information	n Term					_						
Adverse Reaction Term(s)					Me	dDRA	Version			Reaction Duration		

v.21.1 v.21.1

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

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237 Report(s)

Report Information	on	**AEI	R = Adverse R	eaction Re	eport								
Adverse Reaction Report Number	Latest AE Num	R Version ber				Latest Received Date Source of			Autho	arket orization ER Number	Type of Report	Reporter Type	
000106641	()	<mark>1971</mark> -03	-01	1971-0	3-01	Н	lospital			Spontaneous		
Serious r	eport?			[Death:			Disabilit	y:	Congenital Anomaly:			
Yes	3		L	ife Threate	ening:		H	ospitalizatio	n: Yes	Other Med	dically Important Co	onditions:	
Patient Information	on												
Age	Gender		Height Weight				Report	Outcome					
1 Years	Male						Unl	known					
Link / Duplicate F	Report Infor	mation											
	Record	d Type			Link AER** Number								
No duplicate or lin	ked report.												
Product Informat	ion												
Product Desc	ription	Health Pro	oduct Role	Dosag	je Form	Route Administr		Dose	Fre	equency	Therapy Duration	Indication(s)	
MEASLES VACCI	NE 📁	Sus	spect	SOLU	ER FOR JTION ANEOUS								
Adverse Reaction Information	n Term												
Adverse Reaction Term(s)					Me	dDRA	Version			Reaction Duration			

v.21.1

v.21.1

Febrile convulsion

Rash

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Canada Vigilance
Summary of Reported Adverse Reactions

Report Informatio	n	**AE	R = Adverse F	Reaction Re	eport							
Adverse Reaction Report Number	Latest AEF Num		Initial Recei	ved Date	Latest Rece	Source	e of Report	Auth	arket orization LER Number	Type of Report	Reporter Type	
000107586	0		1971-0	1-05	1971-0	1-05	Н	ospital			Spontaneous	
Serious re	eport?				Death:		Disability:			Congenital Anomaly:		
Yes			L	ife Threat	ening:		H	ospitalizatio	n:	Other Me	dically Important Co	onditions:
Patient Information	on											
Age	Gender		Height	\	Weight Report Outcome							
6 Years	Female					Recovered/resolved						
Link / Duplicate R	eport Inform	mation										
	Record	Туре			Link AER** Number							
No duplicate or link	ked report.											
Product Informati	on											
Product Descr	ription	Health Pr	oduct Role	Dosag	je Form	Route Administr		Dose	Fre	equency	Therapy Duration	Indication(s)
MERUVAX 📮		Sus	spect	SOLI	ER FOR JTION FANEOUS	Subcutan	eous	0.05 mL				
Adverse Reaction Information	Term											

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

Canada Vigilanaa

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

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237 Report(s)

Canada vigilance
Summary of Reported Adverse Reactions

Report Informati	on	**AE	**AER = Adverse Reaction Report										
Adverse Reaction Repor Number	T I	ER Version mber	Initial Recei	ved Date	Latest Rece	ived Date	Source	e of Report Auth		arket orization ER Number	Type of Report	Reporter Type	
000110925		0	1972-02	2-07	1972-0	2-07					Spontaneous	Physician	
Serious	report?		Death:					Disabilit	y:		Congenital Anomaly:		
Ye	S		L	ife Threate	ening:		Н	ospitalizatio	n: Yes	Other Med	dically Important Co	onditions:	
Patient Informati	ion												
Age	Gender		Height	V	Veight		Report	Outcome					
20 Months	Male					F	Recovered/resolved						
Link / Duplicate	Report Info	rmation											
	Recor	d Type			Link AER** Number								
No duplicate or lir	nked report.												
Product Informa	tion												
Product Desc	cription	Health Pro	oduct Role	Dosage	e Form	Route Administr		Dose	Fre	equency	Therapy Duration	Indication(s)	
ATTENUVAX	7	Sus	spect	NOT SP	ECIFIED	Parente	ral				1.0 Day(s)		
Adverse Reaction	n Term												
Adverse Reaction Term(s)						Me	edDRA V	Version			Reaction Duration		

v.21.1

Febrile convulsion

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Canada Vigilance
Summary of Reported Adverse Reactions

Report Information	on	**AE	R = Adverse R	eaction Re	eport							
Adverse Reaction Report Number		R Version	Initial Receiv	Latest Received Date Source of Rep			e of Report	Autho	arket orization ER Number	Type of Report	Reporter Type	
000112556		0	1972-07	-11	1972-0	7-11		MAH			Spontaneous	
Serious re	eport?			[Death:			Disabilit	y:	Congenital Anomaly:		
Yes	<u> </u>		Li	fe Threate	ening:		Н	ospitalizatio	n: Yes	Other Med	lically Important Co	onditions:
Patient Information	on											
Age	Gender		Height Weight				Report	Outcome				
7 Months	Male					Unknown						
Link / Duplicate R	Report Infor	rmation										
	Recor	d Type			Link AER** Number							
No duplicate or line	ked report.											
Product Informati	ion											
Product Desc	ription	Health Pro	oduct Role	Dosag	e Form	Route (Dose	Fre	equency	Therapy Duration	Indication(s)
ATTENUVAX		Sus	spect	NOT SP	ECIFIED	Parente	ral	0.5 mL				
Adverse Reaction Information	Term											
Adverse Reaction Term(s)						Me	dDRA V	Version			Reaction Duration	

v.21.1

v.21.1

Oedema

Pyrexia

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

Canada Vigilance
Summary of Reported Adverse Reactions

Report Informatio	n	**AE	R = Adverse R	eaction Re	eport							
Adverse Reaction Report Number	Latest AEF Num		I INITIAL RECEIVED I		ate Latest Received Date		Source	e of Report	Market Authorization Holder AER Number		Type of Report	Reporter Type
000112623	0		1 <mark>972</mark> -09-25		1972-0	1972-09-25					Spontaneous	Physician
Serious re	eport?		Death:		Disability:			y:	Congenital Anomaly:			
Yes			Life Threatening:			Hospitalization:			Other Medically Important Conditions:			
Patient Informatio	on											
Age	Gender		Height	V	Veight		Report	Outcome				
16 Months	Male						Not recovered/not resolved					
Link / Duplicate R	eport Inforr	mation										
	Record	Туре				Link AER*	* Numb	er				
No duplicate or link	ed report.											
Product Information	on											
Product Descr	ription	Health Pro	oduct Role	Dosage Form		Route Administr		Dose	Frequency		Therapy Duration	Indication(s)
LIRUGEN Su		spect	POWDER FOR SOLUTION SUBCUTANEOUS									
Adverse Reaction Term Information												
Adverse Reaction Term(s)						MedDRA Version					Reaction Duration	
Encephalitis	<u>Encephalitis</u>						v.21.1					

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

Report Information	n	**AE	R = Adverse F	Reaction R	Report							
Adverse Reaction Report Number	leaction Report Latest AER Version		Initial Recei	ial Received Date Latest Rece		ived Date	Sourc	e of Report	Market Authorization Holder AER Number		Type of Report	Reporter Type
000113486	C)	1972-12-20		1972-1	1972-12-20		lospital			Spontaneous	
Serious re	port?		Death:		Disability:			Congenital Anomaly:				
Yes			L	_ife Threa	tening:		Н	ospitalization	n: Yes	Other Medically Important Conditions:		
Patient Informatio	Patient Information											
Age	Gender	nder Height			Weight Report C			port Outcome				
6 Years	Male			17 Kilograms		Unknown						
Link / Duplicate Ro	eport Infor	mation										
	Record	d Type			Link AER** Number							
No duplicate or link	ed report.				·							
Product Information												
Product Descr	Product Description Health Product Role		Dosa	ge Form	Route Administr		Dose	Fi	requency	Therapy Duration	Indication(s)	
M-R-VAX		Sus	spect		QUID TANEOUS	Parente	ral					

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	

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Canada Vigilance
Summary of Reported Adverse Reactions

Report Informatio	n	**AE	R = Adverse R	eaction Re	eport							
Adverse Reaction Report Number	Latest AER Version Number		Initial Received Date		Latest Received Date		Sourc	e of Report	Market Authorization Holder AER Number		Type of Report	Reporter Type
000115155	15155 0		1973 -05-09		1973-05-09		Co	mmunity			Spontaneous	
Serious re	eport?		Death:		Disability:			y:	Congenital Anomaly:			
Yes			L	ife Threat	ening:		Н	ospitalizatio	n: Yes	Other Medically Important Conditions:		
Patient Information	on .											
Age	Gender		Height Weight				Report	Outcome				
17 Months	Female					Recovered/resolved						
Link / Duplicate R	eport Inform	mation										
	Record	Туре			Link AER** Number							
No duplicate or link	ked report.											
Product Informati	on											
Product Description Hea		Health Pr	oduct Role	Dosag	je Form	Route Administr		Dose	Fre	equency	Therapy Duration	Indication(s)
ATTENUVAX 📁 Su:		spect	NOT SPECIFIED		Parente	enteral				12.0 Hour(s)		
Adverse Reaction Term nformation												
Adverse Reaction Term(s)					MedDRA Version					Reaction Duration		
Loss of consciousness					v.21.1							

v.21.1

v.21.1

Pyrexia

Seizure

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Report Informati	on	**AE	R = Adverse F	Reaction Re	eport							
Adverse Reaction Repor Number		ER Version mber	Initial Rece	ived Date	Latest F	Received D	ate Sour	ce of Report	Auth	larket orization AER Number	Type of Report	Reporter Type
000115178		0	1972-1	2-27	19	72-12-27	С	ommunity			Spontaneous	
Serious	report?				Death:	<mark>Yes</mark>		Disabili	ty:	Congenital Anomaly:		
Ye	S			_ife Threat	ening:			Hospitalizatio	n:	Other Med	dically Important C	onditions:
Patient Informat	ion											
Age	Gender		Height	V	Veight		Repo	rt Outcoms				
5 Years	Male							Death =				
Link / Duplicate	Report Info	rmation										
	Recor	d Type				Link A	ER** Num	ber				
No duplicate or lir	nked report.											
Product Informa	tion		,									
Product Des	cription	Health Pr	oduct Role	Dosag	je Form		ute of nistration	Dose	Fi	requency	Therapy Duration	Indication(s)
ALLERGY INJEC	TION	Conc	omitant	NOT SF	PECIFIED							
M-R-VAX		Sus	spect		QUID FANEOUS	8						
Adverse Reaction	n Term											
	Ad	verse Reac	tion Term(s)				MedDRA	Version			Reaction Duration	
Conjunctivitis								1.1				
Cyanosis							V.2	1.1				

v.21.1

v.21.1

v.21.1

Pyrexia

Stupor

Vomiting

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

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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
000117513	0	1 <mark>998</mark> -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

Link AER Number Record Type**

No duplicate or linked report.

Product Information

1 Todact Illioillation							
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(s)	MedDRA Version	Reaction Duration
Erythema multiforme =	v.21.1	

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30

237 Report(s)

Summary of Reported Adverse Reaction

**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
000363003	0	<mark>2011</mark> -02-25	2011-02-25	MAH	201100714(0)	Spontaneous	Physician

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

Patient Information

Report 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(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	

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 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
000363773	1	<mark>2011</mark> -03-09	2011-08-19	MAH	WAES1006USA0426 8B1	Spontaneous	Physician

Serious report?	Death:	Disability:	Congenital Anomaly: Ye
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(s)	MedDRA Version	Reaction Duration
Congenital hydronephrosis	v.21.1	
Foetal exposure during pregnancy	v.21.1	
Pyelocaliectasis =	v.21.1	

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 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
000364314	0	<mark>2011</mark> -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

· ationic initial					
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

1 TO GOVE III OF III GUIDE								
Product Description	ct Description		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(s)	MedDRA Version	Reaction Duration
Diarrhoea	v.21.1	
Irritability	v.21.1	
Pyrexia	v.21.1	
Rash	v.21.1	

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 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
000366051	0	<mark>2011</mark> -04-08	2011-04-08	МАН	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	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(s)	MedDRA Version	Reaction Duration
Febrile convulsion	v.21.1	

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Report Information	n	**AE	R = Adverse I	Reaction Re	eport							
Adverse Reaction Report Number	eaction Report Latest AER version Initial Received D		ived Date	Latest Received Date		Source	of Report	Market Authorization Holder AER Number		Type of Report	Reporter Type	
000375833		1	2011-0	8-05	2012-0)2-03	N	МАН	A09	38057A	Spontaneous	Other Health Professional
Serious re Yes	port?			I Life Threato	Death: ening:		Нс	Disabilit espitalizatio		Other Med	Congenital	
Patient Informatio	n											
Age	Gender		Height	V	Veight			Outcome nown				
1 Years Female Link / Duplicate Report Information							UNK	IIOWII				
Link / Duplicate Ki	Record					Link AER*	* Numbe	er				
No duplicate or link		71										
Product Information	on											1
Product Descr	iption	Health Pro	oduct Role	Dosag	e Form	Route Administr		Dose	Fre	equency	Therapy Duration	Indication(s)
MENJUGATE		Conce	omitant	SUSPE	ER FOR ENSION JSCULAR	Unknov	wn					
PREVNAR 13		Conc	omitant		ENSION JSCULAR	Unknov	wn					
PRIORIX-TETRA Suspect POWDER FOR SOLUTION INTRAMUSCULAR		JTION	Subcutan	eous	0.5 mL		Total		Prophylaxis			
Adverse Reaction Information	Adverse Reaction Term Information											
	Adv	erse Reac	tion Term(s)			Me	edDRA V				Reaction Duration	
Acne							v.21.	1				

v.21.1 v.21.1

Arthralgia

Crying

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	

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Report Information	on	**AE	R = Adverse F	Reaction R	eport							
Adverse Reaction Report Number		R Version Initial Received Date Latest Received Date Source of Report Auth		larket orization AER Number	Type of Report	Reporter Type						
000381184	0	1	2011-1	D-11	2011-1	0-11	Co	mmunity			Spontaneous	Physician
Serious re	eport?				Death:			Disabilit	y:		Congenital	Anomaly:
Yes			L	ife Threa	tening:		Н	ospitalizatio	n:	Other Med	dically Important Co	onditions: Yes
Patient Information	on											
Age	Gender		Height	,	Weight		Report	Outcome				
13 Months	Male	76	Centimetres	23	3 Pounds		Un	known				
Link / Duplicate R	Report Infor	mation										
	Record	Туре				Link AER*	* Numb	er				
No duplicate or link	ked report.											
Product Informati	ion											
Product Desc	ription	Health Pr	oduct Role	Dosa	ge Form	Route Administr		Dose	Fı	requency	Therapy Duration	Indication(s)
MENJUGATE Suspect		spect	POWDER FOR SUSPENSION INTRAMUSCULAR		Intramus	cular		Once			Immunisation	
PRIORIX -		Sus	spect	KIT		Intramus	cular					
Adverse Reaction Information	n Term											
	Adv	erse Reac	tion Term(s)			Me	edDRA	Version			Reaction Duration	

v.21.1

Urticaria

Canada Vigilance Summary of Reported Adverse Reactions

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Report	Information	

**AER = Adverse Reaction Report

React	dverse tion Report lumber	Latest AER Version Number	Initial Received Date	Latest Received Date		Market Authorization Holder AER Number	Type of Report	Reporter Type
000	0394411	0	<mark>2011</mark> -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

D-4:4	1 £	:
Patient	intorn	nation

Age	Gender	Height	Weight	Report Outcome
	Unknown			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
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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(s)	MedDRA Version	Reaction Duration
Measles	v.21.1	
Vaccination failure	v.21.1	

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30

237 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
000394681	0	<mark>2011</mark> -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

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

ı	ink / Duplicate Report Information	
	Record Type	Link AER** Number
1	No duplicate or linked report	

Product Information

roduct 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(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	

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

237 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
000405161	2	<mark>2012</mark> -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

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(s)	MedDRA Version	Reaction Duration
Autism spectrum disorder	v.21.1	
Brain injury	v.21.1	

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Report Information	n
Adverse Reaction Report Number	Latest AER V

**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
000411549	0	<mark>2012</mark> -02-14	2012-02-14	МАН	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	Age Gender		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(s)	MedDRA Version	Reaction Duration
Autism spectrum disorder	v.21.1	
Brain injury	v.21.1	

Report Runtime: Initial Received Date: Latest Received Date: Total Number of Reports: 2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30

237 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
000411585	0	<mark>2012</mark> -02-14	2012-02-14	МАН	1202USA01182	Spontaneous	Consumer Or Other Non Health Professional

Serious report?	Death:	Disability:	Congenital Anomaly:	
Yes	Life Threatening:	Hospitalization:	Other Medically Important Conditions: Yes	3

Patient Information

· attotte ittio				
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(s)	MedDRA Version	Reaction Duration
Autism spectrum disorder	v.21.1	
Brain injury	v.21.1	

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

237 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
000411594	0	<mark>2012</mark> -02-14	2012-02-14	МАН	PHHY2012CA011066	Spontaneous	Consumer Or Other Non Health Professional

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

ranem imormation	ent Information	on
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Age	Gender	Height	Weight	Report Outcome
	Male			Unknown

Link / Duplicate Report Information	
Record Type	Link AER** Number
Duplicate	000411585
Duplicate	000405161

Product Information

i roddot iiii oriii dalioii							
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(s)	MedDRA Version	Reaction Duration
Autism spectrum disorder	v.21.1	
Brain injury	v.21.1	

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Canada Vigilance				
Summary of Reported Adverse Reactions				

Report Information	on	**AEI	R = Adverse F	Reaction Re	port								
Adverse Reaction Report Number		ER Version nber	Initial Recei	ved Date	Latest Rece	Latest Received Date Source of Report Auth		Autho	arket orization ER Number	Type of Report	Reporter	Туре	
000414960		1	2012-0	2-28	2012-0)3-01	ľ	ЛАН	A096	66772A	Spontaneous	Physici	an
Serious re	eport?			ı	Death:			Disabilit	y:		Congenital	Anomaly:	
Yes	i		L	ife Threat	ening:		Ho	spitalizatio	n:	Other Med	lically Important Co	onditions:	Yes
Patient Information	on												
Age	Gender		Height	V	Veight		Report	Outcome					
4 Years	Male						Unk	nown					
Link / Duplicate R	eport Info	rmation											
	Recor	d Type				Link AER*	* Numbe	er					
No duplicate or link	ked report.												
Product Informati	ion												
Product Desc	ription	Health Pro	oduct Role	Dosag	e Form	Route Administr		Dose	Fre	equency	Therapy Duration	Indication	on(s)
PEDIACEL		Conco	omitant		ENSION JSCULAR								
PRIORIX =		Sus	spect	K	ΊΤ	Subcutan	eous	0.5 mL		Total	1.0 Day(s)	Prophyl	axis
Adverse Reaction Information	n Term												
	Ad	verse Reac	tion Term(s)			Me	dDRA V	ersion			Reaction Duration		

v.21.1

Immune thrombocytopenic purpura

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

237 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
000415042	0	<mark>2012</mark> -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 Informa	ition			
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(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	

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 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
000430459	0	<mark>2012</mark> -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 Informa	tion			
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/Mil liliters	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: Initial Received Date: Latest Received Date: Total Number of Reports:

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237 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
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(s)	MedDRA Version	Reaction Duration
Cognitive disorder	v.21.1	
Febrile convulsion	v.21.1	

Canada Vigilance Summary of Reported Adverse Reactions

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 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
000431255	0	<mark>2012</mark> -04-24	2012-04-24	МАН	1204USA02486	Spontaneous	Consumer Or Other Non Health Professional

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

ranem imormation	ent Information	on
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Age	Gender	Height Weight		Report Outcome		
6 Years	Male			Unknown		

Link / Duplicate Report Information

Record Type	Link AER** Number
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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(s)	MedDRA Version	Reaction Duration
Cognitive disorder	v.21.1	
Febrile convulsion	v.21.1	

Canada Vigilance Summary of Reported Adverse Reactions

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

237 Report(s)

Indication(s)

Report Information

**AER = Adverse Reaction Report

Adverse Reaction Repor Number	Latest AER Version Number	Initial Received Date	Latest Received Date		Market Authorization Holder AER Number	Type of Report	Reporter Type
000433535	0	<mark>2012</mark> -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	ht Weight Report Outc	
	18 Months	Male			Recovered/resolved

Link / Duplicate Report Information	
Record Type	Link AER** Number
Duplicate	000431260
Duplicate	000430459

Product Information							
Product Description	Health I	Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration

MMR	Suspect	LIQUID SUBCUTANEOUS	Parenteral	0.5 mL	Total	Immunisation	
PEDIACEL	Suspect	SUSPENSION INTRAMUSCULAR	Parenteral		Total	Immunisation	l

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

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

237 Report(s)

Summary of Reported Adverse Reaction

Measles

Mood altered

Personality change

Poor feeding infant

Motor developmental delay

Report Information	Report Information **AER = Adverse Reaction Report											
Adverse Reaction Report Number		ER Version nber	Initial Rece	ived Date	Latest Rece	eived Date	Sourc	e of Report	Autl	Market norization AER Number	Type of Report	Reporter Type
000479974		0	<mark>2012</mark> -1	1-23	2012-1	1-23	Co	mmunity			Spontaneous	Other Health Professional
Serious re	eport?				Death:			Disabilit	y: Yes		Congenital	Anomaly:
Yes				ife Threat	ening:		Н	ospitalizatio	n:	Other Me	dically Important Co	onditions:
Patient Information	on											
Age	Gender		Height	1	Weight		Report	Outcome				
14 Months	Male					Not	recover	ed/not resolve	ed			
Link / Duplicate R	eport Info	rmation										
•		d Type			Link AER** Number							
No duplicate or link	ked report.											
Product Informati	on											
Product Desci	ription	Health Pr	oduct Role	Dosag	ge Form	Route Administr		Dose	F	requency	Therapy Duration	Indication(s)
M-M-R* II		Sus	spect	SOL	ER FOR UTION TANEOUS	Subling	ual	0.5 Milligra	m	Once		Immunisation
Adverse Reaction Information	Adverse Reaction Term Information											
	Adverse Reaction Term(s)		MedDRA Version				Reaction Duration					
Aphasia =							v.21	.1				
Autism spectrum d	isorder						v.21	.1				

v.21.1

v.21.1

v.21.1

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30

237 Report(s)

Canada Vigilance
Summary of Reported Adverse Reactions

Re	oort	Inform	ation

**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
000485357	0	<mark>201</mark> 2-12-18	2012-12-18	Community		Spontaneous	Physician

Serious report?	
Yes	

Death:	Disability:	Congenital Anomaly:
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

No duplicate or linked report.

Product Information

Froduct 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(s)		MedDRA Version	Reaction Duration
Pneumonia 💆		v.21.1	

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

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237 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
000486997	0	<mark>2012</mark> -12-06	2012-12-06	МАН	1211CAN012789	Spontaneous	Consumer Or Other Non Health Professional

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

ranem imormation	ent Information	on
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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(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
<u>Irritability</u>	v.21.1	
Nervousness	v.21.1	
Rash erythematous	v.21.1	
Speech disorder	v.21.1	

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Canada Vigilance						
Summary of Reported Adverse Reactions						

**AER = Adverse Reaction Report												
Adverse Reaction Report Number		R Version	I INITIAL RECEIVED LISTE		Latest Received Date		Sourc	e of Report	Market Authorization Holder AER Number		Type of Report	Reporter Type
000497700		0	2013 -01	1-29	2013-0	1-29		MAH	A10	08886A	Spontaneous	Pharmacist
Serious re				Death: ening:	Disability: Hospitalization: Ye			Congenital Anomaly: Other Medically Important Conditions:				
Patient Information	on .											
Age 12 Months	Gender Female		Height Weight			Report Outcome Recovered/resolved						
Link / Duplicate Report Information						I in In AED+	* N					
No duplicate or link		d Type				Link AER*	<u>" Numb</u>	er				
Product Informati	on											
Product Description He		Health Pr	oduct Role	Dosage Form		Route Administr		Dose	Fre	equency	Therapy Duration	Indication(s)
TRIVIRIX Suspect LIQUID SUBCUTANEOUS			Unknown				1.0 Day(s)	Prophylaxis				
Adverse Reaction Information	Term											
Adverse Reaction Term(s)					Me	dDRA	Version			Reaction Duration		
Asphyxia =					v.21.1							
Cyanosis				v.21.1								
Febrile convulsion					v.21	.1						

Pyrexia

Skin discolouration

Vaccination complication

v.21.1

v.21.1 v.21.1

Canada Vigilance

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Summary of Reported Adverse Reactions

Rash maculo-papular

Varicella

Report Information	n	**AE	R = Adverse R	eaction Re	eport								
Adverse Reaction Report Number		ER Version mber	Initial Recei	ved Date	Latest Rece			Market Authorization Holder AER Number		Type of Report	Reporter	Туре	
000507682		1	2013-0	3-11	2013-0	3-26		MAH A101)15021A	Spontaneous	Physic	ian
Serious re	Serious report? Death:		Death:	Disability:		Congenital Anomaly:							
Yes	;		L	ife Threat	ening:		Н	ospitalizatio	n:	Other Medically Important Conditions: Y		Yes	
Patient Information	on												
Age	Gender		Height	V	Veight		Report	Outcome					
13 Months	Male					F	Recover	ed/resolved					
Link / Duplicate R	Report Info	rmation											
	Recor	d Type				Link AER*	* Numb	er					
No duplicate or line	ked report.												
Product Informati	ion									<u></u>			
Product Desc	ription	Health Pr	oduct Role	Dosag	je Form	Route Administr		Dose	Fi	requency	Therapy Duration	Indicati	on(s)
PRIORIX-TETRA	F	Sus	spect	SOLI	ER FOR JTION USCULAR	Unknov	wn	0.5 mL				Immunis	sation
Adverse Reaction Information	n Term												
	Ad	verse Reac	tion Term(s)			Me	edDRA	Version			Reaction Duration		
Ear infection							v.21	.1					
Measles							v.21						
Pyrexia							v.21	.1					

v.21.1 v.21.1

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Summary of Reported Adverse Reactions

Cough

Pyrexia

Rhinitis

Measles

Rash maculo-papular

Report Informatio	n	**AE	R = Adverse Rea	ction Re	eport							
Adverse Reaction Report Number		R Version	Initial Receive	d Date	Latest Rece	ived Date	Source	e of Report	Auth	arket orization AER Number	Type of Report	Reporter Type
000538516	(0	<mark>2013</mark> -07-03		2013-0	2013-07-03 MAH		B09	04467A	Published	Consumer Or Other Non Health Professional	
Serious re	port?				Death:			Disabilit	y:		Congenital	Anomaly:
Yes			Life	Threat	ening:	Hospitalization: Yes Other Medically Important Conditions			onditions:			
Patient Information	n											
Age	Gender		Height	١	Weight		Report	Outcome				
5 Years	Male							nown				
Link / Duplicate R	eport Infor	mation										
		d Type				Link AER*	* Numbe	er				
No duplicate or link	ed report.											
Product Informati	on											
Product Descr	ription	Health Pr	oduct Role	Dosag	ge Form	Route Administr	~-	Dose	Fr	equency	Therapy Duration	Indication(s)
PRIORIX		Sus	spect	k	KIT	Unknov	wn					Prophylaxis
Adverse Reaction Information	Term											
	Adv	erse Reac	tion Term(s)			Me	edDRA \	/ersion			Reaction Duration	
Conjunctivitis							v.21	.1				

Page	210	
i ago	210	

v.21.1

v.21.1

v.21.1

v.21.1

v.21.1

Report Runtime: Initial Received Date: Latest Received Date: 2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Latest Received Date: Total Number of Reports:

Adverse Reaction Repo Number	rt Latest A	ER Ve	
000569377		0	
Serious	report?		
Ye	es		
Patient Informa	tion		
Age	Gende		
5 Years	Male		
Link / Duplicate	Report Info	ormati	ion
	Reco	rd Ty	ре
No duplicate or li	nked report.		
Product Informa	ation		
Product Des	cription	Hea	alth P

Report Informatio	n **AE	R = Adverse Reaction Re	port				
Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	•	Market Authorization Holder AER Number	Type of Report	Reporter Type
000569377	0	<mark>2013</mark> -11-07	2013-11-07	MAH	2013SA112809	Spontaneous	Other Health Professional
	10	-					

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

Patient informa	uon			
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 Read	ction Term(s)	MedDRA Version	Reaction Duration
Vaccination site cellulitis		v.21.1	

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Reporter Type

Physician

Reaction Report Number	Latest AER Version Number	Initial Received D	Date Latest	t Recei	ved Date	Source of Report	Autho	arket orization ER Number	Type of Report	Reporter T
000570304	0	<mark>2013</mark> -11-14	2	2013-11	1-14	MAH	1310U	SA012271	Spontaneous	Physicia
Serious r	eport?		Death:			Disabilit	y:		Congenital	Anomaly:
Yes	S	Life Th	nreatening:	Yes		Hospitalizatio	n:	Other Med	lically Important C	onditions:
Patient Informati	on									
Age	Gender	Height	Weight			Report Outcome				
1 Years	Male					Unknown				
ink / Duplicate	Report Information									
	Record Type			I	Link AER*	* Number				

Produc	t Inform	mation
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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(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: Initial Received Date: Latest Received Date: Total Number of Reports:

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Thrombocytopenia

Report Informatio	n	**AEI	R = Adverse F	Reaction Re	port							
Adverse Reaction Report Number	Latest AE Num		Initial Recei	ved Date	Latest Rece	ived Date	Source	e of Report	Autho	arket orization ER Number	Type of Report	Reporter Type
000573278	()	2013-1	1-21	2013-1	1-21		МАН	A103	39985A	Spontaneous	Other Health Professional
Serious re	eport?				Death:			Disabilit	y:		Congenital	Anomaly:
Yes			L	ife Threat	ening:		Н	ospitalizatio	n: Yes	Other Med	lically Important Co	onditions: Yes
Patient Information	on											
Age	Gender		Height	V	Veight		Report	Outcome				
27 Months	Female					Not i	recovere	ed/not resolve	ed			
Link / Duplicate R	eport Infor	mation										
	Record	I Туре				Link AER*	* Numb	er				
No duplicate or link	ked report.											
Product Informati	ion											
Product Desci	ription	Health Pro	oduct Role	Dosag	e Form	Route Administr	-	Dose	Fre	equency	Therapy Duration	Indication(s)
PRIORIX-TETRA		Sus	spect	SOLU	ER FOR JTION JSCULAR	Unknov	vn	0.5 mL				Prophylaxis
Adverse Reaction Information	Term											
	Adv	erse Reac	tion Term(s)			Me	dDRA '	Version		ı	Reaction Duration	

v.21.1

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Report Information

**AER = Adverse Reaction Report

Advers Reaction F Numb	Report	Latest AER Version Number	Initial Received Date	Latest Received Date		Market Authorization Holder AER Number	Type of Report	Reporter Type
000578	578	0	<mark>2013</mark> -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	Informa	tion

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(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	

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 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
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	Informa	tion

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(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	

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 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
000593092	0	<mark>2014</mark> -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

			I .		
	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(s)	MedDRA Version	Reaction Duration
Incomplete course of vaccination	v.21.1	

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

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 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
000593247	2	<mark>2014</mark> -03-12	2014-05-07	МАН	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

· ationit initotina				
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(s)	MedDRA Version	Reaction Duration
Pertussis	v.21.1	

Canada Vigilance

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

Market

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Summary of Reported Adverse Reactions

Report Informa	tio	n	
Adverse Reaction Repo	rt	Latest	
000594722			
Serious	re	port?	
Yes			
Patient Informa	tio	n	
Age		Gend	
1 Years		Fema	
Link / Duplicate Report I			
		Re	
Duplicate			
Product Inform	ati	on	

**AER = Adverse Reaction Report

ort	Number	Initial Received Date	Latest Received Date		Authorization Holder AER Number	Type of Report	Reporter Type
2	1	2014-03-17	2014-05-06	MAH	A1063812A	Spontaneous	Physician
us re	port?	-	Death:	Disabilit	ay:	Congenital	Anomaly:

Life Threatening: Hospitalization: Other Medically Important Conditions: Yes

nt imorma	lion			
Age	Gender	Height	Weight	Report Outcome
Years	Female			Unknown

Link / Duplicate Report Information	
Record Type	Link AER** Number
Duplicate	000593247

Route of **Product Description Health Product Role Therapy Duration** Indication(s) **Dosage Form Frequency Dose** Administration MENINGOCOCCAL Suspect **NOT SPECIFIED** Unknown Prophylaxis VACCINES SUSPENSION PEDIACEL Suspect Unknown Prophylaxis INTRAMUSCULAR SUSPENSION INTRAMUSCULAR Prophylaxis PREVNAR 13 Suspect Unknown POWDER FOR PRIORIX-TETRA Prophylaxis Suspect SOLUTION Unknown **INTRAMUSCULAR**

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

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 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
000600134	0	<mark>2014</mark> -04-09	2014-04-09	Community		Spontaneous	Pharmacist

Serious report? Yes

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

Patient Information

L					
	Age	Gender	Height	Weight	Report Outcome
	1 Years	Female			Unknown

Link / Duplicate Report Information **Link AER** Number Record Type** Duplicate E2B_00168660 E2B_02311283 Duplicate

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(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)

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Report Informatio	n
Adverse Reaction Report Number	Lates
000624117	
Serious re	port?
Yes	

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	nitial Received Date Latest Received Date		Source of Report Authorization Holder AER Number		Reporter Type
000624117	0	2014-09-04	2014-09-04	Community		Spontaneous	Physician

Death:	Disability:	Congenital Anomaly:	
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(s)	MedDRA Version	Reaction Duration
Dermatitis	v.21.1	

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Report Information

**AER = Adverse Reaction Report

Adver Reaction Number	Report	Latest AER Version Number	Initial Received Date	Latest Received Date		Market Authorization Holder AER Number	Type of Report	Reporter Type
000628	3633	0	2014 -10-08	2014-10-08	Community		Spontaneous	Physician

Serious report?	Death:	Disability:		Congenital Anomaly:	
Yes	Life Threatening:	Hospitalization: Ye	'es	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(s)	MedDRA Version	Reaction Duration
Joint swelling	v.21.1	
Rash	v.21.1	

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

237 Report(s)

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**AER = Adverse Reaction Report

Report Information

Adverse Reaction Report 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?

Yes

Death:

Disability:

Congenital Anomaly:

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			
Advers	e 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	

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Report Information	
NEODIL IIIIOI III alioi	

**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
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

1 Toddot IIITOTIIIddioii							
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(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	

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Report Information	on	**AE	R = Adverse F	Reaction Re	port								
Adverse Reaction Report Number		ER Version mber	Initial Received Date Latest Received		Received	d Date S	ource of Re	port	Auth	arket orization LER Number	Type of Report	Reporter Type	
000647275		0	2015-0	3-19	20	015-03-19	9	Community	/	2014	ADR039	Spontaneous	Physician
Serious r	eport?			[Death:	Yes		Dis	abilit	y:		Congenital	Anomaly:
Yes	3		L	ife Threate	ening:			Hospitali	zatio	n:	Other Med	dically Important C	onditions:
Patient Information	on												
Age	Gender		Height	V	Veight		Re	eport Outcor	ne				
1 Years	Female			10 k	Kilograms	3		Death		Ę.			
Link / Duplicate F	Report Info	rmation											
	Recor	d Type				Lin	k AER** N	lumber					
No duplicate or lin	ked report.												
Product Informat	ion												
Product Desc	ription	Health Pro	oduct Role	Dosag	e Form		Route of Iministrati	on D	ose	Fr	equency	Therapy Duration	Indication(s)
INFLUENZA VAC	CINE	Sus	spect	NOT SP	ECIFIED)	Unknown				Once		Immunisation
MMR		Sus	spect	LIQ SUBCUT	UID ANEOUS	S	Unknown				Once		Immunisation
Adverse Reaction Information	n Term												
	Adverse Reaction Term(s)				MedI	ORA Version	1			Reaction Duration			

v.21.1

Death

Canada Vigilance Summary of Reported Adverse Reactions

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 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
000663030	0	<mark>2015</mark> -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	Informa	tion

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

Canada Vigilance Summary of Reported Adverse Reactions

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Summary of Reported Adverse Reaction

Report Information **AER = Adverse Reaction Report							
Adverse Reaction Rep Number	Latest AER Versi Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000665499	0	<mark>2015</mark> -10-06	2015-10-06	Community		Spontaneous	Physician

Serious report?

Yes

Death:
Disability:
Congenital Anomaly:
Hospitalization:
Other Medically Important Conditions:

Patient Informa	tion			
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

1 Todact IIII of III ation							
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(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.21.1	
Bronchospasm	v.21.1	

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A 237 Report(s)

Canada Vigilance
Summary of Reported Adverse Reactions

Report Information	on	**AE	R = Adverse R	Reaction Re	eport							
Adverse Reaction Report Number		R Version	ion Initial Received Date Latest Rec		Latest Rece	Received Date		e of Report	Market Authorization Holder AER Number		Type of Report	Reporter Type
000665937		1	2015-1	0-11	2015-1	1-04	Co	mmunity			Spontaneous	Physician
Serious report? Yes			L		Death: fe Threatening:			Disability: Hospitalization:			Congenital	
Patient Information	on											
Age	Gender		Height	V	Veight		Report	Outcome				
12 Months	Female				Recovered/resolved							
Link / Duplicate R	Report Info	rmation										
	Recor	d Type			Link AER** Number							
No duplicate or line	ked report.											
Product Informat	ion											
Product Desc	ription	Health Pro	oduct Role	Dosag	e Form	Route Administr		Dose	Fre	equency	Therapy Duration	Indication(s)
MMRV	MMRV Suspect NOT		NOT SP	PECIFIED	Unknov	vn					Immunisation	
Adverse Reaction Information	n Term											
Adverse Reaction Term(s)					Me	dDRA	Version			Reaction Duration		

v.21.1

v.21.1

Malaise

Rash morbilliform

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Canada Vigilance Summary of Reported Adverse Reactions

Report Information		**AE	R = Adverse F	Reaction I	Report							
Adverse Reaction Report Number	atest AER V Number		Initial Rece	ived Date	E Latest Rece	Received Date So		e of Report	Market Authorization Holder AER Number		Type of Report	Reporter Type
000676417	0		2016-0	4-06	2016-0)4-06	Co	mmunity			Spontaneous	Physician
Serious repo	Serious report? Death:			Death:			Disabilit	y:		Congenital	Anomaly:	
Yes			l	Life Thre	atening:		Н	ospitalizatio	n:	Other Med	dically Important Co	onditions: Yes
Patient Information												
Age	Gender		Height		Weight		Report	Outcome				
12 Months	Female	77	Centimetres	10	0 Kilograms		Unl	known				
Link / Duplicate Report Information										-		
	Record Ty	ре				Link AER*	* Numb	er				
No duplicate or linked	d report.											
Product Information	1											
Product Descript	tion He	alth Pr	oduct Role	Dosa	age Form	Route Administr		Dose	F	requency	Therapy Duration	Indication(s)
AMOXICILLIN		Conc	omitant	NOT S	SPECIFIED							
M-M-R* II		Sus	spect	POWDER FOR SOLUTION SUBCUTANEOL		Subcutan	eous	eous 0.5 mL		Once		Immunisation
Adverse Reaction Tel	erm											
Adverse Reaction Term(s)				MedDRA Version				Reaction Duration				
Rash morbilliform							v.21	.1				

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

237 Report(s)

Summary of Reported Adverse Reaction

Report Informati	on	**/	AER = Adverse F	Reaction Re	eport								
Adverse Reaction Report Number		ER Version	Initial Recei	ived Date	Latest Rec	eived Date	Sourc	Source of Report Author		arket orization LER Number	Type of Report	Reporter T	Гуре
000679333		0	2016-0	5-24	2016-	05-24	Co	mmunity			Spontaneous	Physicia	ลท
Serious report?				Death:			Disabilit	ty:		Congenital	Anomaly:		
Ye	S		L	_ife Threat	ening:		Н	ospitalizatio	n:	Other Me	dically Important Co	onditions:	Yes
Patient Informati	on												
Age	Gender	r Height Weight Report Outcome		Outcome									
4 Years	Female	1	06 Centimetres	18 1	Kilograms		Un	known					
Link / Duplicate	Report Info	ormation											
	Recor	rd Type				Link AER*	* Numb	er					
No duplicate or lin	ked report.	i											
Product Informa	tion												
Product Description Health Product Role			Dosag	ge Form	Route Administr		Dose	Fr	equency	Therapy Duration	Indicatio	n(s)	
INTERNIOUS IDV. DI				01100	ENIGLONI				1				

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(s)	MedDRA Version	Reaction Duration
Rash pruritic	v.21.1	

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

237 Report(s)

**AE	ER = Adverse R	eaction Re	eport								
	Initial Receiv	ved Date	Latest Rece	ived Date	Sourc	e of Report	Auth	orization	Type of Report	Reporter	Туре
0	2016-12	2-05	2016-1	2-05	Со	mmunity			Spontaneous	Consumer Or Other Non Health Professional	
			Death:			Disabilit	v: Yes		Congenital	Anomaly:	
	L				Н			Other Med			Yes
er	Height	\ \ \ \ \ \	Neight		Report	Outcome					
	e.g						ed				
formation								'			
				Link AER*	* Numb	er					
Health P	roduct Role	Dosag	je Form			Dose	Fi	equency	Therapy Duration	Indication	on(s)
M-M-R* II Suspe		POWDER FOR SOLUTION SUBCUTANEOUS					Once			Immunis	ation
Adverse Reaction Term(s)					MedDRA Version				Reaction Duration		
					v.21	.1					
	AER Version lumber 0 er le formation ord Type rt. Health P	AER Version lumber 0 2016-12 L Height le formation ord Type tt. Health Product Role Suspect	AER Version lumber O 2016-12-05 Life Threat Per Height New Heig	Death: Life Threatening: Height Weight Health Product Role Dosage Form Suspect POWDER FOR SOLUTION SUBCUTANEOUS	AER Version lumber Latest Received Date 0 2016-12-05 2016-12-05 Death: Life Threatening: er Height Weight le Not formation ord Type Link AER* t. Health Product Role Dosage Form Suspect SUBCUTANEOUS Route Administr SUBCUTANEOUS Link AER* Route SUBCUTANEOUS AROUTE SUBCUTANEOUS AMDIT Control of the contro	AER Version Initial Received Date Latest Received Date Source 0	AER Version lumber Initial Received Date Latest Received Date Source of Report 0 2016-12-05 2016-12-05 Community Death: Disabilit Life Threatening: Hospitalization	AER Version umber Initial Received Date Latest Received Date Source of Report Auth Holder // Death: Disability: Yes Life Threatening: Height Weight Report Outcome Not recovered/not resolved formation ord Type Link AER** Number T. Health Product Role POWDER FOR SOLUTION SUBCUTANEOUS MedDRA Version	AER Version lumber	Initial Received Date Latest Received Date Source of Report Authorization Holder AER Number Type of Report	AER Version lumber Initial Received Date Latest Received Date Source of Report Authorization Holder AER Number Spontaneous Other Non Profession Death: Death: Disability: Yes Congenital Anomaly: Other Medically Important Conditions: Height Weight Report Outcome Not recovered/not resolved formation ord Type Link AER** Number t. Health Product Role Dosage Form Administration Suspect POWDER FOR SOLUTION SUBCUTANEOUS MedDRA Version Reaction Duration Market Authorization Type of Report Report Report Report Report Outcome Indication Indication Indication Indication Indication Indication Reaction Duration Indication Indication Indication Indication Indication Indication Indication Reaction Duration Indication

v.21.1

v.21.1

v.21.1

v.21.1

v.21.1

Aphasia

Apraxia

Brain injury

Condition aggravated

Decreased eye contact

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Report Information

**AER = Adverse Reaction Report

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	itial Received Date Latest Received Date		Market Authorization Holder AER Number	Type of Report	Reporter Type
000691183	0	<mark>2017</mark> -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(s)	MedDRA Version	Reaction Duration
Fatigue	v.21.1	
Hospitalisation	v.21.1	
Seizure	v.21.1	
Vomiting	v.21.1	

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 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
000700332	0	<mark>2017</mark> -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:

ranem miorination	ent Information	on
-------------------	-----------------	----

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(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	

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30

237 Report(s)

Report Information	n	
	_	
Adverse		

**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
000702090	0	<mark>2017</mark> -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

Link AER Number Record Type**

No duplicate or linked report.

Product Information

1 Todact IIII of III ation							
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(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	

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Reporter Type

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Re	ceived Date	Source of Report	Autho	rket rization ER Number
000715486	0	<mark>2018</mark> -07-09	2018	3-07-09	Community		
Serious re	port?	ı	Death:		Disabilit	y:	
Yes		Life Threat	ening:		Hospitalizatio	n:	Other Med

	Spontaneous	Physici	ian
	Congenital	Anomaly:	
Other Med	lically Important C	onditions:	Yes

Type of Report

Patient	Information	n

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

Froduct 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(s)	MedDRA Version	Reaction Duration
Injection site erythema	v.21.1	
Mass	v.21.1	

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Report Informatio	n **	AER = Adverse Rea	ction Report	t						
Adverse Reaction Report Number	Latest AER Vers Number	on Initial Receive	d Date La	test Rece	ived Date	Source of Report	Auth	arket orization ER Number	Type of Report	Reporter Type
000715985	0	<mark>2018</mark> -07-2	0	2018-0	7-20	Community			Spontaneous	Physician
Serious re	port?	Death: Disability:		y:	Congenital Anomaly:		Anomaly:			
Yes		Life	Threatenin	ng: Yes	Hospitalization:		n:	Other Medically Important Conditions:		onditions:
Patient Informatio	n									
Age	Gender	Height	Weig	ght		Report Outcome				
4 Years	Male	107 Centimetres	15 Kilog	grams	Unknown					

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

Product Information

Froduct 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(s)	MedDRA Version	Reaction Duration
Unresponsive to stimuli	v.21.1	

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Canada Vigilance
Summary of Reported Adverse Reactions

Report Informat	ion	**AE	R = Adverse F	Reaction R	Report								
Adverse Reaction Repor Number	T I	ER Version mber	Initial Recei	tial Received Date Latest Received Date Source of Report Author		Market Authorization Holder AER Number		Type of Report	Reporter	Туре			
000716559		0	2018-0	8-09	2018-0	08-09	Co	mmunity			Spontaneous	Physici	an
Serious	report?				Death:			Disabilit	y:		Congenital	Anomaly:	
Ye	s		L	ife Threa	tening:		Н	ospitalizatio	n:	Other Med	dically Important C	onditions:	Yes
Patient Informat	ion												
Age	Gender		Height		Weight		Report	Outcome					
12 Months	Female	77	Centimetres	9	Kilograms	-							
Link / Duplicate	Report Info	rmation											
	Reco	d Type				Link AER*	* Numb	er					
No duplicate or li	nked report.												
Product Informa	tion											_	
Product Des	cription	Health Pr	oduct Role	Dosa	ge Form	Route Administr		Dose	F	requency	Therapy Duration	Indication	on(s)
MMR		Su	spect		QUID ITANEOUS	Parente	ral					Immunis	ation
Adverse Reaction	n Term												
	Ad	verse Read	tion Term(s)			Me	dDRA	Version			Reaction Duration		
Eyelid ptosis							v.21						
Illrd nerve paraly	sis						v.21	.1					

v.21.1

v.21.1

Movement disorder

Pyrexia

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Rei	nort	Inform	nation
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**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
000718882	0	<mark>2018</mark> -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)
PENADDVI	Concomitant	NOT SPECIFIED	Administration				
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(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	

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

237 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_00168660	0	<mark>2014</mark> -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 Informa	tion			
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)

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

237 Report(s)

Report Information

Product Information

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_00235106	0	<mark>2015</mark> -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 Informa	tion			
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 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
DDEVNAD SINCLE DOSE							

Adverse Reaction Term						
PREVNAR SINGLE DOSE PRE-FILLED SYRINGES AND VIALS	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	0.5 mL		Immunisation
	•	INTRAMUSCULAR				

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

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 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_00276855	0	<mark>2015</mark> -03-13	2015-03-13	МАН	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(s)	MedDRA Version	Reaction Duration
<u>Aphasia</u>	v.21.1	
Autism spectrum disorder	v.21.1	
Brain injury	v.21.1	
Cognitive disorder	v.21.1	
Vaccination failure	v.21.1	

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

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**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_00330016	0	<mark>2015</mark> -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(s)	MedDRA Version	Reaction Duration
Irritability	v.21.1	
Pyrexia	v.21.1	
Vaccination site pain	v.21.1	

Canada Vigilance Summary of Reported Adverse Reactions

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 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_00355781	0	2015-05-26	2015-05-26	МАН	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

· ationit initotina				
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(s)	MedDRA Version	Reaction Duration
Pyrexia	v.21.1	22 Day(s)

Canada Vigilance Summary of Reported Adverse Reactions

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

237 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_00603503	0	<mark>2015</mark> -12-30	2015-12-30	МАН	2014BAX012913	Spontaneous	Consumer Or Other Non Health Professional

Serious report?	Death:	No	Disability:	No	Congenital Anomaly: N	10
Yes	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions: Ye	es

Patient Information

· ationit initotina				
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/HAEMOPHILU S INFLUENZAE VACCINE/PERTUSSIS VACCINE/POLIO VACCINE/TETANUS VACCINE	Suspect	F	Unknown				Immunisation
MEASLES/MUMPS/RUBEL LA 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(s)	MedDRA Version	Reaction Duration
Pertussis	v.21.1	



Canada Vigilance Summary of Reported Adverse Reactions

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

237 Report(s)

Report Information **AER = Adverse Reaction Report

R	Adverse leaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date		Market Authorization Holder AER Number	Type of Report	Reporter Type
E	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(s)	MedDRA Version	Reaction Duration
Febrile convulsion	v.21.1	

Canada Vigilance Summary of Reported Adverse Reactions

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 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_01845217	0	<mark>2018</mark> -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

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Age	Gender	Height	Weight	Report Outcome
1 Years	Male			Unknown

Link / Duplicate Report Information

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(s)	MedDRA Version	Reaction Duration
Autism spectrum disorder	v.21.1	
Pica	v.21.1	
Viral infection	v.21.1	

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Summary of Reported Adverse Reaction

**AER = Adverse Reaction Report

Adverse Reaction Report 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_02063166	0	2018-08-14	2018-08-14	MAH	US2018GSK013137	Published	

Serious report?Death:NoDisability:NoCongenital Anomaly:NoYesLife Threatening:NoHospitalization:YesOther Medically Important Conditions:No

Patient Information

Report 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/PERTA CTIN/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,VA RILRIX III	Suspect		Unknown				Prophylaxis

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	

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 Report(s)

Report Information	n
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**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_02073840	1	2018 -08-20	2018-08-28	MAH	2018SA226582	Published	

Serious report?	
Yes	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
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(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	

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

2019-03-07 - 01:58:06 PM 1970-01-01 to 2018-11-30 N/A

237 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_02187575	0	<mark>2018</mark> -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

i roduct illiorillation							
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(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	