

h Santé da Canada

Canada Vigilance Summary of Reported Adverse Reactions

Report Runtime: Initial Received Date: Latest Received Date: Total Number of Reports: 2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A 139 Report(s)

Brand Name/Active Ingredient: 'EPIPEN', 'EPIPEN 0.3MG/0.3ML AUTO-INJECTOR', 'EPIPEN JR',

'EPIPEN JR 0.15MG/0.3ML AUTO-INJECTOR'

Search Date Criteria: 1965-01-01 to 2017-03-31

Reaction Term(s): All/Tous

Serious report?: Both

Type of Report: All

Source of Report: All

Gender: All

Report Outcome: All

Age: All

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



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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 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
000069879	0	1989-09-25	1989-09-25		Spontaneous	Physician

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
38 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)
EPIPEN	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.15 Milligram	1 every 1 Day(s)		

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.20.0	
Hypoaesthesia	v.20.0	
Injection site pain	v.20.0	
Injection site reaction	v.20.0	

Report Runtime: Initial Received Date: Latest Received Date: Total Number of Reports: 2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 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
000133039	0	2000-07-10	2000-07-10	Community		Spontaneous	Pharmacist

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

Patient Informa	tion			
Age Gender		Height	Weight	Report Outcome
11 Years	Male			Recovered/resolved with sequelae

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

Product	Information	
FIUUUCL	IIIIOIIIIauoii	

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

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Device malfunction	v.20.0	

Report Runtime: Initial Received Date: Latest Received Date: Total Number of Reports: 2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 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
000146613	0	2002-02-15	2002-03-07	Community		Spontaneous	Consumer Or Other Non Health Professional

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
10 Years	Female			Unknown

Link /	Duplicate	Report	Information	

Record Type Link AER** Number

No duplicate or linked report.

Product Information

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Product Description	Health Product Role Dosage Form		Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BRONCHODILATORS	Concomitant	NOT SPECIFIED	Unknown				
EPIPEN	Suspect	SOLUTION INTRAMUSCULAR	Unknown				
SALINE SOAKS	Drug used to treat AE	NOT SPECIFIED	Unknown				
STEROID(S)	Concomitant	NOT SPECIFIED	Unknown				

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Oedema	v.20.0	
Pain	v.20.0	

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 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
000160990	0	2003-05-15	2003-05-15	MAH	0210393	Spontaneous	Physician

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
33 Years	Male		80 Kilograms	Death

Link / Duplicate Report Information

Record Type Link AER** Number

No duplicate or linked report.

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ATROPINE	Concomitant	NOT SPECIFIED	Unknown				
EPINEPHRINE	Concomitant	NOT SPECIFIED	Unknown				
EPIPEN	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.3 Milligram	As required		

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic shock	v.20.0	

Report Runtime: Initial Received Date: Latest Received Date: Total Number of Reports: 2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 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
000164231	0	2003-09-05	2003-09-05	Community		Spontaneous	Other Health Professional

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

Patient Informa	tion			
Age	Gender	Height	Weight	Report Outcome
29 Years	Female			Not recovered/not resolved

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

Product Information

i roddot imormation							
Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
EPIPEN	Suspect	SOLUTION INTRAMUSCULAR	Parenteral	1.0 Dosage forms			

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Burning sensation	v.20.0	
Injection site reaction	v.20.0	

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

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Report Informat	ilo
Adverse Reaction Repo Number	rt
000164276	
Serious	r
N	lo
Patient Informa	tic
Age	
47 Years	
Link / Duplicate	F
No duplicate or li	in
Product Informa	at
Product Des	c

**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
000164276	0	2003-09-05	2003-09-05	Community		Spontaneous	Pharmacist

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

Patient Informa	tion			
Age	Gender	Height	Weight	Report Outcome
47 Years	Female			Recovered/resolved

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

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Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
EPIPEN	Suspect	SOLUTION INTRAMUSCULAR	Parenteral	0.3 Milligram			

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Joint stiffness	v.20.0	
Medication error	v.20.0	
Oedema	v.20.0	
Peripheral coldness	v.20.0	
Skin discolouration	v.20.0	
Tremor	v.20.0	

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139 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
000164792	0	2003-10-01	2003-10-01	Community		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
11 Years	Female			Recovered/resolved

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

Product Information

i roddot imormation							
Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
EPIPEN	Suspect	SOLUTION INTRAMUSCULAR	Unknown				

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Injection site reaction	v.20.0	
Medication error	v.20.0	

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139 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
000165416	0	2003-10-30	2003-10-30	Community		Spontaneous	Other Health Professional

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

Patient Information			
A	Condon		

Age	Gender	Height	Weight	Report Outcome
25 Years	Female			Unknown

Link / Duplicate Report Information

Record Type Link AER** Number

No duplicate or linked report.

Product Information

1 Toddot Information								
	Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
	EPIPEN	Suspect	SOLUTION INTRAMUSCULAR	Unknown				

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Medication error	v.20.0	
Oedema	v.20.0	
Pain	v.20.0	

Report Runtime: Initial Received Date: Latest Received Date: Total Number of Reports: 2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

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Report Information

**AER = Adverse Reaction Report

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date		Market Authorization Holder AER Number	Type of Report	Reporter Type
000165815	0	2003-11-17	2003-11-17	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
48 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)
EPIPEN	Suspect	SOLUTION INTRAMUSCULAR	Unknown				
PHENTOLAMINE	Drug used to treat AE	NOT SPECIFIED	Unknown				

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Injection site reaction	v.20.0	
Medication error	v.20.0	

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

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139 Report(s)

Canada Vigilance
Summary of Reported Adverse Reactions

Report Information	n	**AE	**AER = Adverse Reaction Report									
Adverse Reaction Report Number		ER Version mber	Initial Recei	ved Date	Latest Rece	eived Date	Source	e of Report	Autho	arket orization ER Number	Type of Report	Reporter Type
000165859		0	2003-1	1-17	2003-1	11-17	Cor	mmunity			Spontaneous	Pharmacist
Serious re	eport?			[Death:			Disabilit	y:		Congenital	Anomaly:
No			L	ife Threate	ening:		Н	ospitalizatio	n:	Other Med	dically Important Co	onditions:
Patient Information	on											
Age	Gender		Height	V	Veight		Report	Outcome				
58 Years	58 Years Female				Unk	known						
Link / Duplicate R	eport Info	rmation										
	Recor	d Type				Link AER*	* Numb	er				
No duplicate or link	ced report.											
Product Informati	on											
Product Desci	ription	Health Pro	oduct Role	Dosag	e Form	Route Administr	-	Dose	Fre	equency	Therapy Duration	Indication(s)
EPIPEN		Sus	spect		JTION JSCULAR	Unknov	vn	0.3 Milligra	m			
Adverse Reaction Information	Term											
	Ad	verse Reac	tion Term(s)			Me	edDRA \	Version			Reaction Duration	
Injection site reacti	on						v.20	.0				

Canada Vigilance Summary of Reported Adverse Reactions

Report Runtime: Initial Received Date: Latest Received Date: Total Number of Reports: 2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

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Report Information

**AER = Adverse Reaction Report

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date		Market Authorization Holder AER Number	Type of Report	Reporter Type
000168121	0	2004-02-19	2004-02-19	Community		Spontaneous	Other Health Professional

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

F	Patient Informa	tion			
	Age	Gender	Height	Weight	Report Outcome
	4 Vears	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)
EPIPEN	Suspect	SOLUTION INTRAMUSCULAR	Unknown				

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Injection site pain	v.20.0	
Injection site reaction	v.20.0	

Report Runtime: Initial Received Date: Latest Received Date: Total Number of Reports: 2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 Report(s)

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**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
000168548	0	2004-03-04	2004-03-04	Community		Spontaneous	Pharmacist

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

Patient Informa	tion			
Age	Gender	Height	Weight	Report Outcome
25 Years	Female			Recovered/resolved

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

Product Information

Report Information

1 Todaot IIII of III ation							
Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
EPIPEN	Suspect	SOLUTION INTRAMUSCULAR	Unknown	1.0 Dosage forms			
LIDOCAINE	Drug used to treat AE	NOT SPECIFIED	Subcutaneous				
NITROGLYCERIN	Drug used to treat AE	PATCH	Transdermal				
NORMAL SALINE	Drug used to treat AE	NOT SPECIFIED	Subcutaneous				
PHENTOLAMINE	Drug used to treat AE	NOT SPECIFIED	Subcutaneous				

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Injection site reaction	v.20.0	
Medication error	v.20.0	

Canada Vigilance Summary of Reported Adverse Reactions

Report Runtime: Initial Received Date: Latest Received Date: Total Number of Reports: 2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 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
000169097	0	2004-03-22	2004-03-22	Community		Spontaneous	Other Health Professional

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

Patient Informa	tion			
Age	Gender	Height	Weight	Report Outcome
4 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)
EPIPEN	Suspect	SOLUTION INTRAMUSCULAR	Unknown				

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Injection site reaction	v.20.0	
Medication error	v.20.0	
Skin discolouration	v.20.0	

Report Runtime: Initial Received Date: Latest Received Date: Total Number of Reports: 2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 Report(s)

Report Information	

**AER = Adverse Reaction Report

Advers Reaction R Number	eport	Latest AER Version Number	Initial Received Date	Latest Received Date		Market Authorization Holder AER Number	Type of Report	Reporter Type
0001691	15	0	2004-03-22	2004-03-22	Community		Spontaneous	Pharmacist

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
31 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)
EPIPEN JR	Suspect	SOLUTION INTRAMUSCULAR	Parenteral				

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Injection site reaction	v.20.0	
Paraesthesia	v.20.0	
Skin discolouration	v.20.0	
Swelling	v.20.0	

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

Report Information	n	**AE	R = Adverse F	Reaction Re	eport							
Adverse Reaction Report Number		R Version	Initial Rece	ceived Date Latest Rece		eived Date	Sourc	e of Report	Market Authorization Holder AER Number		Type of Report	Reporter Type
000169139		0	2004-0	3-22	2004-0	3-22	Co	mmunity			Spontaneous	Pharmacist
Serious re	Serious report? Death:			Death:			Disabilit	y:		Congenital	Anomaly:	
No				_ife Threat	ening:		Н	ospitalizatio	n:	Other Med	dically Important Co	onditions:
Patient Information	on											
Age	Gender		Height	١	Neight		Report	Outcome				
18 Years	Male					F	Recovered/resolved					
Link / Duplicate R	eport Info	rmation										
	Recor	d Type				Link AER** Number						
No duplicate or link	ked report.											
Product Informati	ion											
Product Desci	ription	Health Pr	oduct Role	Dosag	je Form	Route Administr		Dose	Fı	requency	Therapy Duration	Indication(s)
EPIPEN		Sus	spect		UTION USCULAR	Unknov	wn					
Adverse Reaction Information	Term											
Adverse Reaction Term(s)			MedDRA Version			Reaction Duration						
Injection site reacti	on					v.20.0						
Medication error						v.20.0						

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

Report Information	Report Information **AER = Adverse Reaction Report											
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
000169643		0	2004-04	l-02	2004-0	04-02	-02 Community				Spontaneous	Pharmacist
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	n											
Age	Gender		Height	\	Veight		Report	Outcome				
8 Years	Male						Un	known				
Link / Duplicate R	eport Info	rmation										
	Recor	d Type				Link AER*	* Numb	er				
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)
EPIPEN		Sus	spect		JTION USCULAR	Unknov	wn					
Adverse Reaction Term Information												
Adverse Reaction Term(s)			MedDRA Version				Reaction Duration					
Injection site pain				v.20.0								
Injection site reacti	on					v.20.0						

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 Report(s)

Report Information

**AER = Adverse Reaction Report

Adverse Reaction Re Number	ort Latest AER Version	Initial Received Date	Latest Received Date		Market Authorization Holder AER Number	Type of Report	Reporter Type
00016965	0	2004-04-02	2004-04-02	Community		Spontaneous	Pharmacist

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

Patient Information

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

Link / Duplicate Report Information

Record Type Link AER** Number

No duplicate or linked report.

Product Information

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Product Description Health Product Role		Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
EPIPEN	Suspect	SOLUTION INTRAMUSCULAR	Unknown				
MORPHINE	Drug used to treat AE	NOT SPECIFIED					
NITROGLYCERIN	Drug used to treat AE	NOT SPECIFIED					
PHENTOLAMINE	Drug used to treat AE	NOT SPECIFIED					

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Injection site necrosis	v.20.0	
Injection site reaction	v.20.0	

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 Report(s)

Report Informat	ion	**AE	R = Adverse F	Reaction Re	eport							
Adverse Reaction Repor Number	T	ER Version mber	Initial Rece	ived Date	Latest Rece	eived Date	Sourc	e of Report	Auth	Market orization AER Number	Type of Report	Reporter Type
000172240		0	2004-0	6-29	2004-0	06-29	Co	mmunity			Spontaneous	Pharmacist
Serious	report?				Death:			Disabilit	y:		Congenital	Anomaly:
N	0		l	_ife Threat	ening:		Н	ospitalizatio	n:	Other Med	dically Important Co	onditions:
Patient Informat	ion											
Age	Gender		Height	\	Neight		Report	Outcome				
4 Years	Male					F	Recover	ed/resolved				
Link / Duplicate	Report Info	rmation										
	Reco	rd Type				Link AER*	* Numb	er				
No duplicate or li	nked report.											
Product Informa	tion											
Product Des	cription	Health Pr	oduct Role	Dosag	je Form	Route Administr		Dose	Fi	requency	Therapy Duration	Indication(s)
EPIPEN JR		Sus	spect		UTION USCULAR	Unknov	vn					
Adverse Reaction	on Term											
	Ad	verse Reac	tion Term(s)			Me	dDRA	Version			Reaction Duration	
Hypoaesthesia							v.20					
Injection site reaction					v.20	0.0						

Medication error

Pallor

v.20.0

v.20.0

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

Canada Vigilance
Summary of Reported Adverse Reactions
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Report Informatio	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	Auth	larket orization AER Number	Type of Report	Reporter Type
000172485		0	2004-07-09 2004-0		7-09	Co	mmunity			Spontaneous	Pharmacist	
Serious re	_			ife Threat	Death:	Disability: Hospitalization: Other M			Other Med	Congenital Anomaly: ledically Important Conditions: Yes		
Patient Informatio				ine imeau	emily.			OSPITALIZATIO	ille.	Other Me	dically important of	onditions: Yes
Age	Gender		Height	V	Neight		Report	Outcome				
26 Years	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	je Form	Route Administr		Dose	Fr	equency	Therapy Duration	Indication(s)
EPIPEN		Sus	spect		UTION USCULAR	Unknov	wn					
Adverse Reaction Information	Term											
Adverse Reaction Term(s)			Me	edDRA	Version			Reaction Duration				
Injection site reaction	on						v.20	0.0				
Medication error							v.20	0.0				

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 Report(s)

Report Information

**AER = Adverse Reaction Report

Re	Adverse eaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date		Market Authorization Holder AER Number	Type of Report	Reporter Type
	000172498	0	2004-07-09	2004-07-09	Community		Spontaneous	Pharmacist

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
50 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)
EPIPEN	Suspect	SOLUTION INTRAMUSCULAR	Unknown	0.3 Milligram			

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Contusion	v.20.0	
Hypoaesthesia	v.20.0	
Injection site reaction	v.20.0	
Pain	v.20.0	
Paraesthesia	v.20.0	

Canada Vigilance Summary of Reported Adverse Reactions

Report Runtime: Initial Received Date: Latest Received Date: Total Number of Reports: 2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31

139 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
000173796	0	2004-08-23	2004-08-23	Community		Spontaneous	Other Health Professional

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

Patient Informa	tion			
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

	auot ninoimanon							
F	Product Description Health Product Role		Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
EPIF	PEN JR	Suspect	SOLUTION INTRAMUSCULAR	Unknown	0.5 Milligram			

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Injection site reaction	v.20.0	
Medication error	v.20.0	

Canada Vigilance

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 Report(s)

Summary of Reported Adverse Reactions

Injection site pain

Medication error

Swelling

Report Information	on	**AE	R = Adverse R	Reaction Re	eport							
Adverse Reaction Report Number		R Version nber	Initial Received Date Latest Received		eived Date	Source	e of Report	Report Authorization Holder AER Numbe		Type of Report	Reporter Type	
000173840	()	2004-08	8-23	2004-0	08-23	Cor	mmunity			Spontaneous	Pharmacist
Serious r	eport?			I	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				
16 Years	Male						Unk	known				
Link / Duplicate R	Report Infor	mation										
	Record	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)
			JTION USCULAR Unknown									
Adverse Reaction Information	n Term											
Adverse Reaction Term(s)					Me	edDRA \	Version			Reaction Duration		

v.20.0

v.20.0 v.20.0

Canada Vigilance Summary of Reported Adverse Reactions

Report Runtime: Initial Received Date: Latest Received Date: Total Number of Reports: 2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 Report(s)

Report Information

**AER = Adverse Reaction Report

Adverse Reaction Report Number	ction Report Latest AER version Initial F		Initial Received Date Latest Received Date		Market Authorization Holder AER Number	Type of Report	Reporter Type
000173873	0	2004-08-23	2004-08-23	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
22 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)
EPIPEN	Suspect	SOLUTION INTRAMUSCULAR	Unknown				

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypoaesthesia	v.20.0	
Injection site reaction	v.20.0	
Medication error	v.20.0	
Swelling	v.20.0	

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

Report Information **AER = Adverse Reaction Report													
Adverse Reaction Report Number		ER Version mber	Initial Receiv	red Date Latest Receiv				Auth	larket orization AER Number	Type of Report	Reporter Type		
000174495		0	2004-09)-14	2005-0)1-18	Co	mmunity			Spontaneous	Physician	
Serious report? Yes			L		Death: Threatening:			Disability: Hospitalization:			Congenital Anomaly: Other Medically Important Conditions: Yes		
Patient Informatio	n												
Age	Gender		Height	V	Veight		Report	Outcome					
28 Years	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 Pro	oduct Role	Dosag	je Form	Route Administr		Dose	Fr	equency	Therapy Duration	Indication(s)	
EPIPEN		Sus	spect		JTION USCULAR	Unknov	vn						
Adverse Reaction Term Information													
	Ad	verse Reac	tion Term(s)			Me	dDRA	Version			Reaction Duration		
Hypoaesthesia							v.20	0.0					
Nerve injury						v.20.0							

Canada Vigilance Summary of Reported Adverse Reactions

Report Runtime: Initial Received Date: Latest Received Date: Total Number of Reports: 2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 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
000174653	0	2004-09-16	2004-09-16	Community		Spontaneous	Other Health Professional

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

Patient Informa	ition			
Age	Gender	Height	Weight	Report Outcome
21 Years	Female			Recovered/resolved

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

Product Information

i roddot imormation							
Product Description	Health Product Role	oduct Role Dosage Form		Dose	Frequency	Therapy Duration	Indication(s)
EPIPEN	Suspect	SOLUTION INTRAMUSCULAR					

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Injection site reaction	v.20.0	
Medication error	v.20.0	

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 Report(s)

Report Informatio	n **AE	R = Adverse Reaction I	Report						
Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Rece	eived Date	Source of Report	Auth	arket orization AER Number	Type of Report	Reporter Type
000175241	0	2004-10-04	2004-10-04 2004-1		Community			Spontaneous	Pharmacist
Serious re	eport?		Death:		Disabilit	y:		Congenital	Anomaly:
Yes		Life Threa	atening:		Hospitalizatio	n: Yes	Other Medically Important Conditions:		onditions:
Patient Informatio	n								
Age	Gender	Height	Weight		Report Outcome				
	Female			F	Recovered/resolved				
Link / Duplicate R	eport Information								
Record Type			Link AER** Number						
No duplicate or link	ed report.								
Product Informati	on								
				Route	of _				

· · · · · · · · · · · · · · · · · · ·							
Product Description	Product Description Health Product Role		Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BENADRYL	Drug used to treat AE	NOT SPECIFIED					
EPIPEN	Suspect	SOLUTION INTRAMUSCULAR					
HOMEOPATHIC PRODUCT	Drug used to treat AE	NOT SPECIFIED					
PHENTOLAMINE	Drug used to treat AE	NOT SPECIFIED					

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Feeling cold	v.20.0	
Hypoaesthesia	v.20.0	
Injection site reaction	v.20.0	
Medication error	v.20.0	
Pallor	v.20.0	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Paraesthesia	v.20.0	

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

Report Information	n	**AE	R = Adverse F	Reaction Re	eport							
Adverse Reaction Report Number		R Version nber	Initial Recei	ived Date	Latest Reco	eived Date	ed Date Source of Report Author		Market Authorization Holder AER Number		Type of Report	Reporter Type
000176279		0	2004-1	0-29	2004-	10-29	Co	mmunity			Spontaneous	Pharmacist
Serious re	eport?				Death:		Disability:		Congenital Anomaly:		Anomaly:	
No			L	ife Threat	ening:		Н	ospitalizatio	n:	Other Me	dically Important Co	onditions:
Patient Information	on											
Age	Gender		Height	V	Veight	Report Outcome						
36 Years	Female					F	Recover	ed/resolved				
Link / Duplicate R	eport Infor	mation										
	Recor	d Type			Link AER** Number							
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)
EPIPEN	EPIPEN Suspect SOLUTION INTRAMUSCULAR			Unkno	wn							
Adverse Reaction Information	Term											
Adverse Peaction Term(s)					M	V4DD V	Varsion			Peaction Duration		

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Contusion	v.20.0	
Injection site reaction	v.20.0	
Medication error	v.20.0	
Pallor	v.20.0	
Swelling	v.20.0	

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 Report(s)

Report Information	**AER = Adverse Reaction Report

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000176362	0	2004-10-29	2004-10-29	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
9 Years	Male			Unknown

Link / Duplicate Report Information

		Record Type	Link AER** Number
No duplica	ate or linke	d report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
EPIPEN	Suspect	SOLUTION INTRAMUSCULAR	Unknown				

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Erythema	v.20.0	
Injection site reaction	v.20.0	
Medication error	v.20.0	
Oedema	v.20.0	
Pallor	v.20.0	

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

Report Informatio	Report Information **AER = Adverse Reaction Report											
Adverse Reaction Report Number		R Version nber	Initial Rece	ived Date	ved Date Latest Recei		Sourc	e of Report	Market Authorization Holder AER Number		Type of Report	Reporter Type
000176977	(0	2004-1	1-15	2004-1	1-15	Co	mmunity			Spontaneous	Pharmacist
Serious re	port?				Death: Disability:			Congenital Anomaly:				
Yes			l	Life Threat	ening:		Н	ospitalizatio	n: Yes	Other Med	dically Important Co	onditions:
Patient Informatio	n											
Age	Gender		Height Weight		Report Outcome							
13 Years	Female					Recovered/resolved						
Link / Duplicate R	eport Info	mation										
-	Recor	d Type			Link AER** Number							
No duplicate or link	ed report.											
Product Information	on											
Product Description Health Product Role Dos		Dosag	e Form	Route Administr		Dose	Fr	equency	Therapy Duration	Indication(s)		
EPIPEN		Sus	spect		JTION JSCULAR	Unknov	vn	0.3 Milligrar	m			
NITROGLYCERIN	PASTE	Drug used	to treat AE	NOT SP	ECIFIED							

Adverse Reaction	Term
Information	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Injection site reaction	v.20.0	
Medication error	v.20.0	

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

Report Informatio	n	**AE	R = Adverse R	Reaction Re	eport							
Adverse Reaction Report Number		ER Version mber	Initial Recei	Initial Received Date Latest Received		eived Date			Auth	Market norization AER Number	Type of Report	Reporter Type
000179932		0	1997-0	4-28	1997-0	04-28	Co	mmunity			Spontaneous	Pharmacist
Serious re	port?				Death:			Disabilit	y:		Congenital	Anomaly:
Yes			L	ife Threat	ening:		Н	ospitalizatio	n: Yes	Other Me	dically Important Co	onditions:
Patient Informatio	n											
Age	Gender		Height	1	Neight		Report	Outcome				
17 Years	Female	163	3 Centimetres	54	Kilograms	Not	recover	ed/not resolve	ed			
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	F	requency	Therapy Duration	Indication(s)
EPIPEN		Sus	spect		UTION USCULAR	Unknov	wn					
Adverse Reaction Information	Term											
	Ad	verse Reac	tion Term(s)			Me	dDRA	Version			Reaction Duration	
Nerve injury							v.20					
Pain							v.20	0.0				

Report Runtime: Initial Received Date: Latest Received Date: Total Number of Reports: 2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 Report(s)

Report Information

**AER = Adverse Reaction Report

Adverse Reaction Rep Number	Latest AER Version Number	Initial Received Date	Latest Received Date		Market Authorization Holder AER Number	Type of Report	Reporter Type
000180210	0	2005-02-03	2005-02-03	Community		Spontaneous	Pharmacist

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

Patient Information

Age	Gender	Height	Weight	Report Outcome	
3 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)
EPIPEN	Suspect	SOLUTION INTRAMUSCULAR	Unknown	0.3 Milligram			

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Agitation	v.20.0	
Injection site reaction	v.20.0	
Tongue discolouration	v.20.0	

Canada Vigilance Summary of Reported Adverse Reactions

Report Runtime: Initial Received Date: Latest Received Date: Total Number of Reports: 2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 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
000182672	0	2005-03-30	2005-03-30	Community		Spontaneous	Other Health Professional

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

Patient	Informati	tion

Age	Gender	Height	Weight	Report Outcome
	Female			Recovered/resolved

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)
EPIPEN	Suspect	SOLUTION INTRAMUSCULAR	Unknown				

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Injection site pain	v.20.0	
Palpitations	v.20.0	
Skin discolouration	v.20.0	

Canada Vigilance Summary of Reported Adverse Reactions

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 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
000185843	0	2005-05-24	2005-05-24	Community		Spontaneous	Consumer Or Other Non Health Professional

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

Patient Information

L					
	Age	Gender	Height	Weight	Report Outcome
		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)
EPIPEN	Suspect	SOLUTION INTRAMUSCULAR	Unknown				
NITROGLYCERIN	Drug used to treat AE	PATCH					

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Injection site reaction	v.20.0	
Medication error	v.20.0	

Canada Vigilance Summary of Reported Adverse Reactions

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 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
000189296	0	2005-08-17	2005-08-17	Community		Spontaneous	Other Health Professional

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male			Recovered/resolved

Link / Duplicate Report Information

Record Type Link AER** Number

No duplicate or linked report.

Product Information

1 Todact information							
Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
EPIPEN	Suspect	SOLUTION INTRAMUSCULAR	Unknown				
NITROGLYCERIN	Drug used to treat AE	PATCH	Unknown				

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Injection site reaction	v.20.0	
Medication error	v.20.0	
Pallor	v.20.0	

Canada Vigilance Summary of Reported Adverse Reactions

Report Runtime: Initial Received Date: Latest Received Date: Total Number of Reports: 2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 Report(s)

Summary of Reported Adverse

Report Information		**AE	ER = 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
	000189297	0	2005-08-17	2005-08-17	Community		Spontaneous	Other Health Professional

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

Patient Information				
Age	Gender	Height	Weight	Report Outcome
Female				Recovered/resolved

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

i roduct imormation							
Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
EPIPEN	Suspect	SOLUTION INTRAMUSCULAR	Unknown				
PHENTOLAMINE	Drug used to treat AE	NOT SPECIFIED	Unknown				

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Injection site reaction	v.20.0	
Pain	v.20.0	
Pallor	v.20.0	

Canada Vigilance Summary of Reported Adverse Reactions

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 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
000189317	0	2005-08-17	2005-08-17	Community		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	
43 Years	Female			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)
EPIPEN	Suspect	SOLUTION INTRAMUSCULAR	Unknown				

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Feeling cold	v.20.0	
Injection site reaction	v.20.0	
Medication error	v.20.0	

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 Report(s)

Report Information	**AER = Adverse Reaction Report

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000189993	0	2005-09-02	2005-09-02	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
	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)
EPIPEN	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Injection site discomfort	v.20.0	
Medication error	v.20.0	
Pallor	v.20.0	

Canada Vigilance Summary of Reported Adverse Reactions

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 Report(s)

Summary of Reported Adverse Reaction

Injection site reaction

Skin discolouration

Report Information	**AER = Adverse Reaction Report											
Adverse Reaction Report Number		ER Version mber	Initial Receiven Dat		te Latest Received Date		Sourc	e of Report	Market Authorization Holder AER Number		Type of Report	Reporter Type
000192562		0	2005-1	0-27	2005-1	0-27	Co	mmunity			Spontaneous	Other Health Professional
Serious re	eport?			ı	Death:			Disabilit	y:		Congenital	Anomaly:
No			L	ife Threat	ening:		Н	ospitalizatio	n:	Other Med	dically Important Co	onditions:
Patient Information	n											
Age	Gender		Height	V	Veight		Report Outcome					
11 Years	Female				Unknown							
Link / Duplicate R	eport Info	rmation										
	Recor	d Type				Link AER*	* Numb	er				
No duplicate or link	ked report.											
Product Informati	on											
Product Desci	ription	Health Pr	oduct Role	Dosag	e Form	Route Administr		Dose	Fre	equency	Therapy Duration	Indication(s)
EPIPEN JR S		Sus	spect		JTION JSCULAR	Unknov	vn					
Adverse Reaction Information	Adverse Reaction Term Information											
Adverse Reaction Term(s)				Me	dDRA	Version			Reaction Duration			

v.20.0

v.20.0

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 Report(s)

**AER = Adverse Reaction Report

Adverse Reaction Repo	rt Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000192564	0	2005-10-27	2005-10-27	Community		Spontaneous	Pharmacist

Serious report?

No

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

Patient Information

Report Information

Age	Gender	Height	Weight	Report Outcome
17 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)
EPIPEN	Suspect	SOLUTION INTRAMUSCULAR	Unknown				

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Injection site reaction	v.20.0	
Skin discolouration	v.20.0	

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 Report(s)

Report Information	n	**AE	R = Adverse Re	action Re	eport							
Adverse Reaction Report Number	Latest AEI Num		Initial Receive	ed Date	d Date Latest Receiv		ived Date Source of Re		Auth	larket orization AER Number	Type of Report	Reporter Type
000194330	0)	2005-12-	2005-12-09		2-09	Co	mmunity			Spontaneous	Pharmacist
Serious re	Serious report?				Death:			Disabilit	y:		Congenital	Anomaly:
No	No Life *		e Threat	ening:		H	ospitalizatio	n:	Other Med	dically Important Conditions:		
Patient Informatio	n			•								
Age	Gender		Height		Veight	Report Outcome						
62 Years	Female					F	Recovered/resolved					
Link / Duplicate Re	eport Infor	mation										
	Record	Туре				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)
EPIPEN JR		Sus	spect		JTION USCULAR	Unknov	vn	0.3 mL				

Adverse R	eaction	Term
Informatio	n	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypoaesthesia	v.20.0	
Injection site reaction	v.20.0	
Paraesthesia	v.20.0	
Skin discolouration	v.20.0	

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 Report(s)

Canada Vigilance Summary of Reported Adverse Reactions

Report Informatio	n	**AE	R = Adverse F	Reaction Re	eport							
Adverse Reaction Report Number		ER Version nber	Initial Recei	ved Date	Latest Rece	test Received Date Source of Repo			Market Authorization Holder AER Number		Type of Report	Reporter Type
000194334		0	2005-12-09 2005-12-			2-09	Co	mmunity			Spontaneous	Pharmacist
Serious report? Death:		Death:		Disability:				Congenital	Anomaly:			
Yes	Yes Life Threatening:			Н	ospitalizatio	n: Yes	Other Med	dically Important Co	onditions:			
Patient Informatio	n											
Age	Gender		Height	V	Neight		Report	Outcome				
9 Years	Female				Recovered/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	je Form	Route Administr		Dose	F	requency	Therapy Duration	Indication(s)
EPIPEN JR		Sus	spect		UTION USCULAR	Unknov	wn					
Adverse Reaction Information	Term											
	Adv	verse Reac	tion Term(s)			Me	MedDRA Version				Reaction Duration	
Cardiovascular disc	order						v.20	.0				
Skin discolouration							v.20	.0				

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 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
000196648	0	2006-01-31	2006-01-31	MAH		Spontaneous	Consumer Or Other Non Health Professional

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type Link AER** Number	r
-------------------------------	---

No duplicate or linked report.

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
EPIPEN JR	Suspect	SOLUTION INTRAMUSCULAR	Unknown		Once		

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypoaesthesia	v.20.0	
Injection site reaction	v.20.0	
Medication error	v.20.0	
Skin discolouration	v.20.0	

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

Reaction Duration

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 Report(s)

	n			Reaction Re	7,00.0								
Adverse Reaction Report Number		R Version nber	Initial Rece	ived Date	Date Latest Received Da		Source of Report Auth		Auth	arket orization LER Number	Type of Report	Reporter	Туре
000196837	()	2006-0	2-02	2006-0	02-02	Com	nmunity			Spontaneous	Pharma	cist
Serious report?				Death: Disability:				Congenital Anomaly:					
Yes				Life Threat	ening:		Но	spitalizatio	n:	Other Med	dically Important Co	onditions:	Yes
Patient Informatio	n												
Age	Gender		Height	١	Weight Report Outcome								
11 Years	Female		<u> </u>					nown					
Link / Duplicate R	eport Infor	mation											
•	-	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	Fre	equency	Therapy Duration	Indication	on(s)
EPIPEN				UTION USCULAR	Unknov	wn							

Information			
Adver	se Reaction Term(s)	MedDRA Version	
Contusion		v.20.0	
		22.2	

Feeling cold v.20.0 Haemorrhage v.20.0 Injection site reaction v.20.0 Medication error v.20.0 Paraesthesia v.20.0 Skin discolouration v.20.0

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 Report(s)

Reaction Duration

**AFR = Adverse Reaction Report

Adverse Reaction Term(s)

Report Information

Information

Injection site pain

Injection site reaction

Dizziness

Swelling

Adverse Reaction Report Number	Latest AER Numb		Initial Received D		ate Latest Received Date		Source	of Report	Market Authorization Holder AER Number		Type of Report	Reporter Type
000201734	0		2006-05-03		2006-05-03		M	ИАН			Spontaneous	Physician
Serious r	eport?				Death: Disability:		y:	Congenital Anomaly:		Anomaly:		
No				Life Threat	ening:		Но	spitalizatio	n:	Other Medically Important Conditions:		
Patient Information	on											
Age	Gender		Height	V	Neight		Report C	Outcome				
44 Years	Female						Unkr	nown				
Link / Duplicate R	Report Inform	ation										
	Record 1	уре			Link AER** Number							
No duplicate or lin	ked report.											
Product Informat	ion											
Product Desc	ription H	ealth Pro	oduct Role	Dosag	je Form	Route Administr	-	Dose	Fre	equency	Therapy Duration	Indication(s)
EPIPEN		Sus	pect		UTION USCULAR	Intramuso	cular					
TYLENOL EXTRA STRENGTH TAB		rug used	to treat AE	TAE	BLET	Unknov	vn					

MedDRA Version

v.20.0

v.20.0 v.20.0

v.20.0

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 Report(s)

Injection site pain

Oedema

Injection site reaction

Report Informatio	n	**AE	R = Adverse F	Reaction Re	eport							
Adverse Reaction Report Number	Latest AEF Num		Initial Received Date L		Latest Received Date		Sourc	e of Report	Auth	arket orization AER Number	Type of Report	Reporter Type
000202182	0		2006-05-15 2006-05		5-15		MAH			Spontaneous	Pharmacist	
Serious re	port?				Death:			Disabilit	y:	Congenital Anomaly:		
Yes			L	ife Threat	ening:		Н	ospitalizatio	n: Yes			
Patient Informatio	n											
Age	Gender		Height Weight			Report	Outcome					
	Female					Not i	recovere	ed/not resolve	ed			
Link / Duplicate R	eport Inform	mation										
	Record	Туре				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	Fre	equency	Therapy Duration	Indication(s)
EPIPEN		Sus	spect		UTION USCULAR	Unknov	vn					
PHENTOLAMINE		Drug used	to treat AE	NOT SF	PECIFIED	Unknov	vn					
Adverse Reaction Information	Term											
	Adve	erse Reac	tion Term(s)			Me	dDRA	Version			Reaction Duration	

Page	47
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v.20.0 v.20.0

v.20.0

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 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
00020	2190	0	2006-05-15	2006-05-15	MAH		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
41 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type Link AER** Number

No duplicate or linked report.

Product Information

i roddot iiiioiiiidtioii							
Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
EPIPEN	Suspect	SOLUTION INTRAMUSCULAR	Unknown	0.3 Milligram	Once		
NITROGLYCERIN PASTE	Drug used to treat AE	NOT SPECIFIED	Unknown				

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Feeling cold	v.20.0	
Injection site pain	v.20.0	
Injection site pain	v.20.0	
Pallor	v.20.0	

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 Report(s)

Report Information	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	Market norization AER Number	Type of Report	Reporter Type
000202196		0	2006-05-15 2006-05)5-15		MAH			Spontaneous	Pharmacist
Serious re	eport?				Death:			Disabilit	y:	Congenital Anomaly:		
No				Life Threat	ening:		Н	ospitalizatio	n:	Other Medically Important Conditions:		
Patient Information	on											
Age	Gender		Height	V	Weight		Report	Outcome				
37 Years	Female					F	Recover	ed/resolved				
Link / Duplicate R	eport Info	rmation								_		
	Record Type					Link AER*	* Numb	er				
No duplicate or line	ked report.											
Product Informati	ion											
Product Desc	ription	Health Pr	oduct Role	Dosag	ge Form	Route Administr		Dose	F	requency	Therapy Duration	Indication(s)
EPIPEN JR		Sus	spect		UTION USCULAR	Unknov	wn	0.5 Milligra	m	Once		
Adverse Reaction Information	Term											
	Ad	verse Reac	tion Term(s)			Me	edDRA	Version			Reaction Duration	
Injection site pain							v.20					
Injection site react	on						v.20	0.0				

v.20.0

Pallor

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 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
000209554	0	2006-09-21	2006-09-21	Community		Spontaneous	Physician

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

Patient Information

L					
	Age	Gender	Height	Weight	Report Outcome
	61 Years	Male			Death

Link / Duplicate Report Information

Record Type Link AER Number**

No duplicate or linked report.

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACCUPRIL	Concomitant	TABLET					
EPIPEN	Suspect	SOLUTION INTRAMUSCULAR					
EPIPEN	Drug used to treat AE	SOLUTION INTRAMUSCULAR	Subcutaneous				
LOPRESOR	Suspect	NOT SPECIFIED					

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Angioedema	v.20.0	
Cardiac arrest	v.20.0	
Drug ineffective	v.20.0	
Drug interaction	v.20.0	
Dyspnoea	v.20.0	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Laryngeal oedema	v.20.0	
Loss of consciousness	v.20.0	
Medication error	v.20.0	
Oedema mouth	v.20.0	
Respiratory arrest	v.20.0	

Report Runtime: Initial Received Date: Latest Received Date: Total Number of Reports: 2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 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
000216002	0	2007-03-05	2007-03-05	MAH	K200700207	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
47 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)
EPIPEN	Suspect	SOLUTION INTRAMUSCULAR	Unknown				

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Feeling cold	v.20.0	
Hypoaesthesia	v.20.0	
Injection site reaction	v.20.0	
Pain	v.20.0	
Pallor	v.20.0	

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 Report(s)

Summary of Reported Adverse Reactions

Report Information	on	**AE	R = Adverse F	Reaction Re	eport							
Adverse Reaction Report Number		ER Version mber	Initial Recei	ved Date	Latest Rece	eived Date	Source	e of Report	Auth	Market norization AER Number	Type of Report	Reporter Type
000216589		0	2007-0	3-16	2007-0	3-16		MAH	K20	0700286	Spontaneous	Physician
Serious re	eport?			l	Death:			Disabilit	y: Yes		Congenital	Anomaly:
Yes	5		L	ife Threat	ening:		H	ospitalizatio	n:	Other Med	dically Important Co	onditions:
Patient Information	on											
Age	Gender		Height	V	Neight		Report	Outcome				
	Female					Not	recovere	d/not resolve	ed			
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	F	requency	Therapy Duration	Indication(s)
EPIPEN		Sus	spect		UTION USCULAR	Unknov	wn					
Adverse Reaction Information	n Term					_						
	Ad	verse Reac	tion Term(s)			Me	edDRA	/ersion			Reaction Duration	
Injury							v.20					
Medication error				v.20	.0							

Canada Vigilance Summary of Reported Adverse Reactions

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 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
000217559	0	2007-04-12	2007-04-12	MAH	K200700408	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	
20 Years	Male			Recovered/resolved	

Link / Duplicate Report Information

Record Type
Link AER** Number

No duplicate or linked report.

Product Information

i roddot iiiioiiiidtioii							
Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
EPIPEN	Suspect	SOLUTION INTRAMUSCULAR	Unknown	0.3 Milligram	Once		
NITROGLYCERIN PASTE	Drug used to treat AE	NOT SPECIFIED	Unknown				

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Medication error	v.20.0	

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 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
000219631	0	2007-06-12	2007-06-12	MAH	K200700670	Spontaneous	Consumer Or Other Non Health Professional

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

D-4:4	1 £	4:
Patient	intorn	nation

Age	Gender	Height	Weight	Report Outcome	
	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)
EPIPEN	Suspect	SOLUTION INTRAMUSCULAR	Unknown	0.3 Milligram	Once		
PHENTOLAMINE	Drug used to treat AE	NOT SPECIFIED	Unknown				

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Feeling cold	v.20.0	
Hypoaesthesia	v.20.0	
Injection site pain	v.20.0	
Injection site reaction	v.20.0	
Medication error	v.20.0	
Pallor	v.20.0	

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 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
000220226	0	2007-06-19	2007-08-20	MAH	K200700707	Spontaneous	Physician

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

Patient Information

Age	Gender	Height	Weight	Report Outcome	
4 Years	Male		15 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)
ASTHMA MEDICATIONS	Concomitant	NOT SPECIFIED	Unknown				
EPIPEN JR	Suspect	SOLUTION INTRAMUSCULAR	Intradermal	0.15 Milligram		1.0 Day(s)	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cardiac arrest	v.20.0	

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 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
000223970	0	2007-10-04	2007-10-04	MAH	K200701232	Spontaneous	Consumer Or Other Non Health Professional

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

Patient Information	on
---------------------	----

Age	Gender	Height	Weight	Report Outcome	
41 Years	Female		70 Kilograms	Recovered/resolved	

Link / Duplicate Report Information

Record Type	Link AER** Number
-------------	-------------------

No duplicate or linked report.

Product Information

Floduct information							
Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ALTACE	Concomitant	CAPSULE					
BENADRYL	Drug used to treat AE	NOT SPECIFIED					
EPIPEN	Suspect	SOLUTION INTRAMUSCULAR	Intradermal	0.3 Milligram			
FLOVENT	Concomitant	NOT SPECIFIED					
MARVELON 28 TAB	Concomitant	TABLET			_		_
VENTOLIN	Concomitant	NOT SPECIFIED					

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Drug administration error	v.20.0	
Pain	v.20.0	

Canada Vigilance Summary of Reported Adverse Reactions

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 Report(s)

Skin discolouration

Report Information **AER = Adverse Reaction Report												
Adverse Reaction Report Number		R Version	Initial Recei	ved Date	Latest Rece	eived Date	Sourc	e of Report	Auth	arket orization LER Number	Type of Report	Reporter Type
000224222		0	2007-1	0-12	2007-1	10-12		MAH	K200	701279	Spontaneous	Pharmacist
Serious r					Death:			Disabilit			Congenital	
Yes	1		L	ife Threat	ening:		Н	<u>ospitalizatio</u>	n:	Other Med	dically Important Co	onditions: Yes
Patient Information	on											
Age	Gender		Height	V	Veight		Report	Outcome				
40 Years	Female						Unl	known				
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 Pro	oduct Role	Dosag	e Form	Route Administr		Dose	Fre	equency	Therapy Duration	Indication(s)
EPIPEN		Sus	spect		JTION JSCULAR	Intraderr	mal	0.3 Milligra	m	Once		
PHENTOLAMINE		Drug used	to treat AE	NOT SP	ECIFIED							
Adverse Reaction Information	n Term											
	Ad	verse Reac	tion Term(s)			Me	dDRA	Version		l	Reaction Duration	

v.20.0

Canada Vigilance Summary of Reported Adverse Reactions

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 Report(s)

Report Informa	t
Adverse Reaction Repo Number	1
000226317	
Serious	,
Y	E
Patient Informa	1
Age	l
52 Years	
Link / Duplicate	•
No duplicate or I	i
Product Inform	ê
Product Des	5
	Ī

**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
000226317	0	2007-01-04	2007-01-04	MAH	VER000912007	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
52 Years	Female			Recovered/resolved

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

ation

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
EPIPEN	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.3 Milligram	2 every 1 Day(s)		
TWINJECT AUTO- INJECTOR	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Device malfunction	v.20.0	
Injury	v.20.0	
Medication error	v.20.0	
Pain	v.20.0	
Pallor	v.20.0	

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 Report(s)

Report Informat	tio	n	
Adverse Reaction Repo Number	rt	Lates	
000303474			
Serious report?			
N	lo		
Patient Information			
Age		Gen	
23 Years		Fem	
Link / Duplicate	R	eport l	

**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
000303474	0	2008-05-15	2008-05-15	Community		Spontaneous	Pharmacist

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

Patient Informa	tion			
Age	Gender	Height	Weight	Report Outcome
23 Years	Female			Unknown

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

B	1
Product	Information

1 Todact IIII of III ation							
Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
EPIPEN JR	Suspect	SOLUTION INTRAMUSCULAR	Subdermal				Product used for unknown indication

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Contusion	v.20.0	
Injection site discolouration	v.20.0	
Injury associated with device	v.20.0	
Peripheral coldness	v.20.0	

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 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
000309082	0	2008-07-17	2008-07-17	Community		Spontaneous	Consumer Or Other Non Health Professional

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
	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)
EPIPEN	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Anaphylactic reaction

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.20.0	
Device malfunction	v.20.0	
Needle issue	v.20.0	
Presyncope	v.20.0	

Report Runtime: Initial Received Date: Latest Received Date: Total Number of Reports: 2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 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
000310932	0	2008-09-05	2008-09-05	MAH	K200801014	Spontaneous	Consumer Or Other Non Health Professional

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

Patient Information	ation
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Age	Gender	Height	Weight	Report Outcome
27 Years	Female			Recovered/resolved

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)
EPIPEN	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.3 Milligram	Once		Rubber sensitivity
IUD NOS	Concomitant		Intra-uterine				
MORPHINE	Concomitant	NOT SPECIFIED	Unknown				

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Drug ineffective	v.20.0	
Dyspnoea	v.20.0	
Throat irritation	v.20.0	

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 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
000311802	0	2008-09-29	2008-09-29	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	on
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· attorit iiii oi iiia				
Age	Gender	Height	Weight	Report Outcome
7 Years	Female	48 Inches	44 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)
EPIPEN JR	Suspect	SOLUTION INTRAMUSCULAR	Parenteral		As required		Anaphylactic reaction

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Device failure	v.20.0	
Drug interaction	v.20.0	
Hospitalisation	v.20.0	

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 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
000313195	1	2008-10-30	2008-11-10	MAH	K200801242	Spontaneous	Lawyer

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

Patient Information

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

Link / Duplicate Report Information

Link AER Number Record Type**

No duplicate or linked report.

Product Information

i roddot iiiioriiiatioii							
Product Description	escription Health Product Role Dosage Fo		Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
EPIPEN	Suspect	SOLUTION INTRAMUSCULAR	Unknown	0.3 Milligram	Once		Product used for unknown indication

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Accidental exposure to product	v.20.0	
Device malfunction	v.20.0	
Infection	v.20.0	
Peripheral swelling	v.20.0	
Physical disability	v.20.0	

Canada Vigilance Summary of Reported Adverse Reactions

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 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
000313723	0	2008-10-22	2008-10-22	Community		Spontaneous	Consumer Or Other Non Health Professional

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type Link AER** Number

No duplicate or linked report.

Product Information

Product Description	Health Product Role	Product Role Dosage Form		Dose	Frequency	Therapy Duration	Indication(s)
EPIPEN	Suspect	SOLUTION INTRAMUSCULAR	Unknown				Anaphylactic reaction

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Device failure	v.20.0	
Drug administration error	v.20.0	

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 Report(s)

Report Information	

**AER = Adverse Reaction Report

Adverse Reaction Repo Number	Latest AER Version Number	Initial Received Date	Latest Received Date		Market Authorization Holder AER Number	Type of Report	Reporter Type
000317678	1	2009-02-03	2009-03-16	MAH	K200900094	Spontaneous	Consumer Or Other Non Health Professional

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

Patient Information	ation
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Age	Gender	Height	Weight	Report Outcome
57 Years	Female		47 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)
EPIPEN	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.3 Milligram	Once		Anaphylactic reaction

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Drug ineffective	v.20.0	
Injection site pain	v.20.0	
Injury associated with device	v.20.0	
Needle issue	v.20.0	

Canada Vigilance Summary of Reported Adverse Reactions

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31

139 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
000327819	0	2009-07-31	2009-07-31	MAH	K200900900	Spontaneous	Consumer Or Other Non Health Professional

Serious report?	Death:	Disability:	Congenital Anomaly:
No	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)
EPIPEN	Suspect	SOLUTION INTRAMUSCULAR	Unknown	0.3 Milligram	Once		Anaphylactic reaction

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Device malfunction	v.20.0	
Drug ineffective	v.20.0	

Canada Vigilance

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 Report(s)

Summary of Reported Adverse Reactions

Report Information	on	**AE	R = Adverse F	Reaction Re	eport							
Adverse Reaction Report Number		ER Version mber	Initial Recei	nitial Received Date Latest Receiv		eived Date	Sourc	ce of Report Author		larket orization AER Number	Type of Report	Reporter Type
000327856		0	2009-0	8-03	2009-0	8-03		MAH	K20	0900904	Spontaneous	Pharmacist
Serious r	eport?			ı	Death:			Disabilit	y:		Congenital	Anomaly:
No)		L	ife Threat	ening:		Н	ospitalizatio	n:	Other Med	lically Important Co	onditions:
Patient Informati	on											
Age	Gender		Height	V	Neight		Report	Outcome				
	Female					F	Recover	ed/resolved				
Link / Duplicate F	_ink / Duplicate Report Information											
	Recor	d Type				Link AER*	* Numb	er				
No duplicate or lin	ked report.											
Product Informat	tion											_
Product Desc	cription	Health Pr	oduct Role	Dosag	je Form	Route Administr		Dose	Fr	equency	Therapy Duration	Indication(s)
EPIPEN		Sus	spect		UTION USCULAR	Unknov	vn	0.3 Milligra	m			Anaphylactic reaction
Adverse Reaction Information	n Term											
	Ad	verse Reac	tion Term(s)			Me	dDRA	Version			Reaction Duration	
Device malfunctio	n						v.20					
Drug ineffective						v.20.0						
Needle issue							v.20	.0				

Report Runtime: Initial Received Date: Latest Received Date: Total Number of Reports: 2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 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
000327871	1	2009-08-03	2009-10-16	МАН	K200900878	Spontaneous	Consumer Or Other Non Health Professional

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

D - 41.		1 6	
Patie	nt	Intor	mation

Age	Gender	Height	Weight	Report Outcome
52 Years	Female			Unknown

Link / Duplicate Report Information	
Record Type	Link AER** Number
Dunlicate	000327282

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AVAPRO	Concomitant	TABLET	Unknown				
BETASERON	Concomitant	POWDER FOR SOLUTION SUBCUTANEOUS	Unknown				
EPIPEN	Suspect	SOLUTION INTRAMUSCULAR	Unknown		Once		Drug hypersensitivity
SEPTRA	Concomitant	TABLET	Unknown				

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Accidental overdose	v.20.0	
Myocardial infarction	v.20.0	
Overdose	v.20.0	

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 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
000330646	0	2009-09-29	2009-09-29	MAH	K200901169	Published	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
24 Years	Female			Recovered/resolved

Link / Duplicate Report Information	
Record Type	Link AER** Number
Duplicate	000330254

Product Information							
Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
EPIPEN	Suspect	SOLUTION	Intramuscular	5.0 Milligram	Once		Anaphylactic

•		9	Administration			• •	、
EPIPEN	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	5.0 Milligram	Once		Anaphylactic reaction
Adverse Reaction Term							

Information		
Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Accidental overdose	v.20.0	
Akinesia	v.20.0	
Anuria	v.20.0	
Blood bicarbonate decreased	v.20.0	
Blood creatine phosphokinase increased	v.20.0	
Blood glucose increased	v.20.0	
Blood lactic acid increased	v.20.0	
Blood potassium decreased	v.20.0	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood pressure decreased	v.20.0	
Blood pressure increased	v.20.0	
Brain natriuretic peptide increased	v.20.0	
Catheterisation cardiac abnormal	v.20.0	
Chest pain	v.20.0	
Ejection fraction decreased	v.20.0	
Electrocardiogram ST segment depression	v.20.0	
Epinephrine increased	v.20.0	
Heart rate increased	v.20.0	
Hypertension	v.20.0	
Hypotension	v.20.0	
Incorrect dose administered	v.20.0	
Nausea	v.20.0	
Oxygen saturation decreased	v.20.0	
Pallor	v.20.0	
Palpitations	v.20.0	
Peripheral coldness	v.20.0	
Respiratory rate increased	v.20.0	
Shock	v.20.0	
Sinus tachycardia	v.20.0	
Stress cardiomyopathy	v.20.0	
Tachycardia	v.20.0	
Tremor	v.20.0	
Troponin T increased	v.20.0	
Vomiting	v.20.0	

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 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
000346444	1	2010-06-28	2010-07-22	МАН	K201000799	Spontaneous	Consumer Or Other Non Health Professional

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
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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)
EPIPEN JR	Suspect	SOLUTION INTRAMUSCULAR	Unknown	0.15 Milligram	Once		Product used for unknown indication

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Accidental exposure to product	v.20.0	
Injection site nerve damage	v.20.0	
Injury associated with device	v.20.0	

Report Runtime: Initial Received Date: Latest Received Date: Total Number of Reports: 2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31

139 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
000377110	0	2011-08-22	2011-08-22	Community		Spontaneous	Other Health Professional

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

Patient Informat	tion			
Age	Gender	Height	Weight	Report Outcome
	Not specified			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)
EPIPEN	Suspect	SOLUTION INTRAMUSCULAR	Parenteral				Product used for unknown indication

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Device deployment issue	v.20.0	
Drug administration error	v.20.0	
Injection site coldness	v.20.0	
Injection site pain	v.20.0	
Injection site pallor	v.20.0	
Injury associated with device	v.20.0	
Neuralgia	v.20.0	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Product quality issue	v.20.0	

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 Report(s)

Canada Vigilance
Summary of Reported Adverse Reactions

Report Information	n	**AE	R = Adverse R	eaction Re	port							
Adverse Reaction Report Number		ER Version mber	Initial Recei	ved Date	Latest Rec	eived Date	Sourc	e of Report	Auth	larket orization AER Number	Type of Report	Reporter Type
000385172		0	2011-11	1-08	2011-	11-08		MAH	K20	1101052	Spontaneous	Pharmacist
Serious re			L	Death: Yes ife Threatening:			Disability: Hospitalization: Yes		Congenital Anomaly: Other Medically Important Conditions:			
Patient Information	on											
Age	Gender		Height	V	Veight		Report	Outcome				
	Male						D	eath				
Link / Duplicate R	eport Info	rmation										
	Recor	d Type				Link AER*	* Numb	er				
No duplicate or line	ked report.											
Product Informati	ion											
Product Desc	ription	Health Pr	oduct Role	Dosag	e Form	Route Administr		Dose	Fr	equency	Therapy Duration	Indication(s)
EPIPEN		Sus	spect		JTION JSCULAR	Intramus	cular	0.9 Milligra	m	Total		Anaphylactic reaction
Adverse Reaction Information	n Term											
	Ad	verse Reac	tion Term(s)			Me	edDRA	Version			Reaction Duration	
Drug ineffective							v.20	0.0				

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31

139 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
000399563	2	2012-01-03	2012-02-04	MAH	2011314930	Spontaneous	Other Health Professional

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
	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)
EPIPEN	Suspect	SOLUTION INTRAMUSCULAR	Unknown				Product used for unknown indication

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Accidental exposure to product	v.20.0	
Contusion	v.20.0	
Expired product administered	v.20.0	
Injection site coldness	v.20.0	
Injection site pallor	v.20.0	
Pain	v.20.0	

Canada Vigilance Summary of Reported Adverse Reactions

Report Runtime: Initial Received Date: Latest Received Date: Total Number of Reports: 2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 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
000403504	0	2012-01-23	2012-01-23	Community		Spontaneous	Consumer Or Other Non Health Professional

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

· anomi miorination				
Age	Gender	Height	Weight	Report Outcome
51 Years	Female			Not recovered/not resolved

	Lin	k /	Dup	olicate	Report	Information
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Record Type	Link AER** Number

No duplicate or linked report.

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
EPIPEN	Suspect	SOLUTION INTRAMUSCULAR	Parenteral	0.3 Milligram	As required		Anaphylactic reaction

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Device deployment issue	v.20.0	
Device failure	v.20.0	
Drug ineffective	v.20.0	

Report Runtime: Initial Received Date: Latest Received Date: Total Number of Reports: 2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 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
000435788	0	2012-05-14	2012-05-14	Community		Spontaneous	Pharmacist

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
36 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)
DIPHENHYDRAMINE	Suspect	NOT SPECIFIED	Intravenous (not otherwise specified)				Product used for unknown indication
EPIPEN	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Product used for unknown indication

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Somnolence	v.20.0	

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 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
000437056	3	2012-05-14	2012-07-11	MAH	2012111189	Spontaneous	Consumer Or Other Non Health Professional

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

Patient Information

Age	Gender	Height Weight		Report Outcome	
	Male			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)
ANTICONVULSANT(S)	Concomitant	INJECTION					
EPIPEN	Suspect	SOLUTION INTRAMUSCULAR	Unknown				Product used for unknown indication

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Accidental exposure to product	v.20.0	
Product quality issue	v.20.0	
Seizure	v.20.0	

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 Report(s)

Report Information

**AER = Adverse Reaction Report

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000443457	3	2012-06-13	2012-07-19	MAH	2012136148	Spontaneous	Pharmacist

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

Patient Information

i ationit iiiioiiiia				
Age	Gender	Height Weight		Report Outcome
15 Years	Female			Recovered/resolved

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

Product Information

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Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
EPIPEN	Suspect	SOLUTION INTRAMUSCULAR	Unknown				Anaphylactic reaction

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.20.0	1 Day(s)
Drug ineffective	v.20.0	1 Day(s)
Needle issue	v.20.0	
Wrong technique in product usage process	v.20.0	

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 Report(s)

Report Information

**AER = Adverse Reaction Report

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000451951	1	2012-07-20	2012-08-10	MAH	2012165215	Spontaneous	Other Health Professional

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

Patient	Information	
		=

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type Link AER** Number

No duplicate or linked report.

Product Information

i roduct iiiioriiiatioii							
Product Description Health Product Role		Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
EPIPEN	Suspect	SOLUTION INTRAMUSCULAR	Unknown				Hypersensitivity

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Drug ineffective	v.20.0	
Product lot number issue	v.20.0	
Product quality issue	v.20.0	

Report Runtime: Initial Received Date: Latest Received Date: Total Number of Reports: 2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 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
000456208	2	2012-08-09	2012-09-11	MAH	2012186859	Spontaneous	Consumer Or Other Non Health Professional

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

Patient Information	ation
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Age	Gender	Height	Weight	Report Outcome
5 Years	Male			Recovering/resolving

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)
EPIPEN	Suspect	SOLUTION INTRAMUSCULAR	Unknown				Product used for unknown indication

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Injection site laceration	v.20.0	
Product quality issue	v.20.0	

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 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
000466076	1	2012-09-19	2012-10-15	MAH	2012226768	Spontaneous	Consumer Or Other Non Health Professional

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

D - 41.		1 6	
Patie	nt	Intor	mation

Age	Gender	Height	Weight	Report Outcome
	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)
EPIPEN 0.3MG/0.3ML AUTO-INJECTOR	Suspect	SOLUTION INTRAMUSCULAR	Unknown				Product used for unknown indication

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Tremor	v.20.0	

Report Runtime: Initial Received Date: Latest Received Date: Total Number of Reports: 2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 Report(s)

Report Informa	tion	

**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
000523214	1	2013-05-03	2013-05-26	MAH	2013131415	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
	Not specified			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)
EPIPEN JR	Suspect	SOLUTION INTRAMUSCULAR	Unknown				Product used for unknown indication

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Injection site injury	v.20.0	
Needle issue	v.20.0	
Product quality issue	v.20.0	

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 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
000536459	0	2013-06-25	2013-06-25	MAH	2013185041	Spontaneous	Consumer Or Other Non Health Professional

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

Patient Information

· attotte iiii o					
Age	Gender	Height	Weight	Report Outcome	
	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)
EPIPEN	Suspect	SOLUTION INTRAMUSCULAR	Unknown				Product used for unknown indication

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.20.0	

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 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
000536547	2	2013-06-25	2013-07-15	MAH	2013182364	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
77 Years	Female		90 Kilograms	Recovered/resolved

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)
ADALAT XL - SRT	Concomitant	TABLET (EXTENDED- RELEASE)					
EPIPEN	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	1.0 Dosage forms	As required		Anaphylactic reaction
RAMIPRIL	Concomitant	NOT SPECIFIED					
RANITIDINE	Concomitant	NOT SPECIFIED					
SYNTHROID	Concomitant	NOT SPECIFIED					

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Drug effect incomplete	v.20.0	
Product lot number issue	v.20.0	

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 Report(s)

Report Information **AER = Adverse Reaction Report													
Adverse Reaction Report Number		ER Version nber	Initial Recei	ved Date	Latest Rece	eived Date	Source	of Report	Auth	arket orization LER Number	Type of Report	Reporter '	Туре
000540440		0	2013-07	7-11	2013-0	7-11	ľ	ИАН	2013	3199164	Spontaneous	Pharmacist	
Serious re	eport?			[Death:			Disabilit	y:		Congenital	Anomaly:	
Yes			L	ife Threate	ening:		Но	spitalizatio	n:	Other Med	dically Important Co	onditions:	Yes
Patient Information	n												
Age	Gender		Height	V	Veight		Report	Outcome					
	Male						Unk	nown					
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 Pr	oduct Role	Dosag	e Form	Route Administr	-	Dose	Fr	equency	Therapy Duration	Indication	on(s)
EPIPEN		Sus	spect		JTION JSCULAR	Intramuso	cular					Arthropod	sting
Adverse Reaction Information	Term												
	Adverse Reaction Term(s)			Me	edDRA \	/ersion			Reaction Duration				
Haemorrhage							v.20.	0					

Report Runtime: Initial Received Date: Latest Received Date: Total Number of Reports: 2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 Report(s)

Report Information	**AER = Adverse Reaction Report

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000553251	0	2013-09-07	2013-09-07	Community		Spontaneous	Physician

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

Age	Gender	Height	Weight	Report Outcome
2 Years	Male	90 Centimetres	31 Pounds	Unknown

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
EPIPEN JR 0.15MG/0.3ML AUTO-INJECTOR	Suspect	SOLUTION INTRAMUSCULAR	Unknown		Once		Anaphylactic reaction

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Device failure	v.20.0	

Canada Vigilance Summary of Reported Adverse Reactions

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 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
000554061	1	2013-09-11	2013-09-20	MAH	2013256893	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 Hei		Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

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)
EPIPEN	Suspect	SOLUTION INTRAMUSCULAR	Unknown				Hypersensitivity

Link AER Number**

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Drug hypersensitivity	v.20.0	
Reaction to drug excipients	v.20.0	

Canada Vigilance Summary of Reported Adverse Reactions

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 Report(s)

Re	port	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
000557404	34	2013-09-24	2017-02-27	Clinical Study	PHHY2013CA091175	Study	

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

Patient Information

Age Gender		Height Weight		Report Outcome
47 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)
AMOXICILLIN SODIUM/CLAVULANATE POTASSIUM	Suspect		Unknown				Pulmonary congestion
AVAMYS	Concomitant	SPRAY, METERED DOSE	Unknown				Product used for unknown indication
BENADRYL	Suspect	NOT SPECIFIED	Unknown	2.0 Dosage forms			Sensation of foreign body, Pharyngeal oedema, Hypersensitivity, Food allergy

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
BENADRYL	Suspect	TABLET					Sensation of foreign body, Pharyngeal oedema, Hypersensitivity, Food allergy
BENADRYL	Suspect	TABLET					Sensation of foreign body, Pharyngeal oedema, Hypersensitivity, Food allergy
BENADRYL	Suspect	TABLET					Sensation of foreign body, Pharyngeal oedema, Hypersensitivity, Food allergy
EPIPEN JR 0.15MG/0.3ML AUTO-INJECTOR	Suspect	SOLUTION INTRAMUSCULAR	Unknown				Product used for unknown indication
FLOVENT	Concomitant	NOT SPECIFIED	Unknown				Product used for unknown indication
IRON	Concomitant	NOT SPECIFIED	Unknown				Anaemia
REACTINE	Suspect	NOT SPECIFIED	Unknown	10.0 Milligram			Seasonal allergy, Pruritus generalised, Nasal congestion
REACTINE	Suspect		Unknown				Seasonal allergy, Pruritus generalised, Nasal congestion
REACTINE	Suspect	_	Unknown	0.5 Dosage forms	_	4.0 Month(s)	Seasonal allergy, Pruritus generalised, Nasal congestion
XOLAIR	Suspect		Subcutaneous				Eczema, Asthma

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
XOLAIR	Suspect		Subcutaneous				Eczema, Asthma
XOLAIR	Suspect		Subcutaneous				Eczema, Asthma
XOLAIR	Suspect		Subcutaneous				Eczema, Asthma
XOLAIR	Suspect		Subcutaneous				Eczema, Asthma
XOLAIR	Suspect		Subcutaneous				Eczema, Asthma
XOLAIR	Suspect		Subcutaneous				Eczema, Asthma
XOLAIR	Suspect		Subcutaneous				Eczema, Asthma
XOLAIR	Suspect		Subcutaneous				Eczema, Asthma
XOLAIR	Suspect		Subcutaneous				Eczema, Asthma
XOLAIR	Suspect		Subcutaneous				Eczema, Asthma
XOLAIR	Suspect		Subcutaneous				Eczema, Asthma
XOLAIR	Suspect		Subcutaneous				Eczema, Asthma
XOLAIR	Suspect		Subcutaneous		1 every 2 Week(s)		Eczema, Asthma
XOLAIR	Suspect		Subcutaneous				Eczema, Asthma
XOLAIR	Suspect		Subcutaneous				Eczema, Asthma
XOLAIR	Suspect		Subcutaneous				Eczema, Asthma
XOLAIR	Suspect		Subcutaneous				Eczema, Asthma
XOLAIR	Suspect		Subcutaneous				Eczema, Asthma
XOLAIR	Suspect		Subcutaneous				Eczema, Asthma
XOLAIR	Suspect		Subcutaneous				Eczema, Asthma

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
XOLAIR	Suspect		Subcutaneous				Eczema, Asthma
XOLAIR	Suspect	POWDER FOR SOLUTION SUBCUTANEOUS	Subcutaneous	375.0 Milligram	1 every 2 Week(s)		Eczema, Asthma

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain	v.20.0	
Abdominal pain upper	v.20.0	
Anaphylactic shock	v.20.0	
Asthma	v.20.0	
Breast pain	v.20.0	
Bronchitis	v.20.0	
Cellulitis	v.20.0	
Cellulitis streptococcal	v.20.0	
Cough	v.20.0	
Decreased appetite	v.20.0	
Dizziness	v.20.0	
Drug ineffective	v.20.0	
Eczema	v.20.0	
Fatigue	v.20.0	
Feeling hot	v.20.0	
Food allergy	v.20.0	
Food intolerance	v.20.0	
Generalised erythema	v.20.0	
Head injury	v.20.0	
Headache	v.20.0	
Headache	v.20.0	
Heart rate decreased	v.20.0	
Hypersensitivity	v.20.0	
Inappropriate schedule of drug administration	v.20.0	
Injection site erythema	v.20.0	
Injection site pain	v.20.0	
Injection site reaction	v.20.0	3 Day(s)

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Insomnia	v.20.0	
Mastitis	v.20.0	
Nasal congestion	v.20.0	
Osteoarthritis	v.20.0	
Pain in extremity	v.20.0	
Pharyngeal oedema	v.20.0	
Poor quality sleep	v.20.0	
Product use in unapproved indication	v.20.0	
Pruritus	v.20.0	
Pruritus generalised	v.20.0	
Pulmonary congestion	v.20.0	
Rash erythematous	v.20.0	
Rhinorrhoea	v.20.0	
Secretion discharge	v.20.0	
Self esteem decreased	v.20.0	
Sensation of foreign body	v.20.0	
Skin infection	v.20.0	
Skin lesion	v.20.0	
Sneezing	v.20.0	
Swelling face	v.20.0	
Viral upper respiratory tract infection	v.20.0	
Vitamin D deficiency	v.20.0	
Vomiting	v.20.0	

Canada Vigilanaa

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A 139 Report(s)

Canada Vigilance
Summary of Reported Adverse Reactions

Report Informatio	n	**AE	R = Adverse F	Reaction Re	eport							
Adverse Reaction Report Number	Latest AER Numb		Initial Recei	ved Date	Latest Rece	eived Date	Source	e of Report	Auth	larket orization AER Number	Type of Report	Reporter Type
000566062	0		2013-1	0-24	2013-1	10-24	1	MAH	201	3297594	Spontaneous	Pharmacist
Serious re	eport?			I	Death:			Disabilit	y:		Congenital	Anomaly:
Yes			L	ife Threat	ening:		Н	spitalizatio	n:	Other Med	dically Important C	onditions: Yes
Patient Informatio	on .											
Age	Gender		Height	V	Veight		Report	Outcome				
	Unknown						Unk	nown				
Link / Duplicate R	eport Inform	nation										
•	Record					Link AER*	* Numbe	er				
No duplicate or link	ked report.											
Product Information	on											
Product Descr	ription	Health Pro	oduct Role	Dosag	je Form	Route Administr		Dose	Fi	requency	Therapy Duration	Indication(s)
EPIPEN		Sus	spect		JTION USCULAR	Unknov	wn					Product used for unknown indication
Adverse Reaction Information	Term											
	Adverse Reaction Term(s)				Me	edDRA \	/ersion			Reaction Duration		
Drug ineffective							v.20	0				

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 Report(s)

Report Information	on	**AE	R = Adverse F	Reaction Re	eport							
Adverse Reaction Report Number		ER Version mber	Initial Recei	ved Date	Latest Rec	eived Date	ved Date Source of Report Auth		Auth	arket orization ER Number	Type of Report	Reporter Type
000573362		0	2013-1	1-22	2013-	11-22		MAH	20138	31025342	Spontaneous	Pharmacist
Serious r	eport?]	Death:			Disabilit	y:		Congenital	Anomaly:
Yes	S		L	ife Threat	ening: Yes		Н	ospitalizatio	n:	Other Med	lically Important Co	onditions:
Patient Informati	on											
Age	Gender		Height	V	Veight		Report	Outcome				
58 Years	Male					F	Recover	ed/resolved				
Link / Duplicate I	Report Info	rmation										
	Reco	d Type				Link AER*	* Numb	er				
No duplicate or lin	ked report.											
Product Informat	tion											
Product Desc	ription	Health Pro	oduct Role	Dosag	je Form	Route Administr		Dose	Fre	equency	Therapy Duration	Indication(s)
CRESTOR		Conce	omitant	TAE	BLET							
EPIPEN		Sus	spect		SOLUTION RAMUSCULAR Unknown						Allergy to arthropod bite	
Adverse Reactio Information	n Term											
Adverse Reaction Term(s)				Me	dDRA	Version			Reaction Duration			

v.20.0

Device failure

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 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
000574189	0	2013-11-28	2013-11-28	MAH	2013340185	Spontaneous	Consumer Or Other Non Health Professional

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Duplicate	000575146

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
EPIPEN	Suspect	SOLUTION INTRAMUSCULAR	Unknown				Food allergy

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Condition aggravated	v.20.0	
Expired product administered	v.20.0	
Hypersensitivity	v.20.0	
Reaction to drug excipients	v.20.0	

Canada Vigilance Summary of Reported Adverse Reactions

Report Runtime: Initial Received Date: Latest Received Date: Total Number of Reports: 2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 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
000575146	0	2013-12-03	2013-12-03	MAH	2013S1026464	Spontaneous	Consumer Or Other Non Health Professional

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

Patient Information

	Age	Gender	Height	Weight	Report Outcome
		Female			Unknown

Link / Duplicate Report Information	
Record Type	Link AER** Number
Duplicate	000574189

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
EPIPEN	Suspect	SOLUTION INTRAMUSCULAR	Unknown				Food allergy

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Condition aggravated	v.20.0	
Expired product administered	v.20.0	
Hypersensitivity	v.20.0	
Reaction to drug excipients	v.20.0	

Report Runtime: Initial Received Date: Latest Received Date: Total Number of Reports: 2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 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
000576823	0	2013-12-16	2013-12-16	Community		Spontaneous	Physician

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
61 Years	Male			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)
ELOCOM	Concomitant	NOT SPECIFIED					
EPIPEN 0.3MG/0.3ML AUTO-INJECTOR	Suspect	SOLUTION INTRAMUSCULAR	Unknown				Product used for unknown indication
TETRACYCLINE	Concomitant	NOT SPECIFIED					

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Drug administration error	v.20.0	
Drug dispensing error	v.20.0	
Myalgia	v.20.0	

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 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
000578641	0	2013-12-23	2013-12-23	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

· attom in it	ation			
Age	Gender	Height	Weight	Report Outcome
	Female	66 Inches	207 Pounds	Recovered/resolved

Link / Duplicate Report Information

Record Type Link AER** Number

No duplicate or linked report.

Product Information

Product information							
Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
ACTEE A GRAPPES NOIRES	Concomitant	CAPSULE					
CANNEBERGE	Concomitant	CAPSULE					
EPIPEN 0.3MG/0.3ML AUTO-INJECTOR	Suspect	SOLUTION INTRAMUSCULAR	Unknown	1.0 Dosage forms			Anaphylactic reaction
FEMINEX MULTI: ADRIEN GAGNON MULTI VITAMINS ET MINÉRAUX	Concomitant	TABLET					
GINKGO BILOBA (ADRIEN GAGNON)	Concomitant	NOT SPECIFIED					
MELATONIN	Concomitant	NOT SPECIFIED					
TROPHIC A WOMAN'S FORMULA	Concomitant	TABLET					

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

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.20.0	
Dyspnoea	v.20.0	
Headache	v.20.0	
Tremor	v.20.0	

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 Report(s)

Report Information	n	**AE	R = Adverse F	Reaction R	eport								
Adverse Reaction Report Number		R Version nber	Initial Rece	ived Date	Latest Rece	eived Date	Sourc	e of Report	Auth	Market norization AER Number	Type of Report	Reporter T	уре
000579796	()	2013-1	2-20	2013-1	2-20		MAH	2013	S1026126	Spontaneous	Physicia	เท
Serious re	eport?				Death:			Disabilit	y:		Congenital	Anomaly:	
Yes				Life Threat	tening:		Н	lospitalizatio	n:	Other Med	dically Important Co	onditions:	Yes
Patient Information	n												
Age	Gender		Height	,	Weight		Report	Outcome					
4 Years	Male					F	Recover	red/resolved					
Link / Duplicate R	eport Infor	mation								_			
	Record	d Type				Link AER*	* Numb	er					
Duplicate						00058	0630						
Product Informati	on												
Product Desci	ription	Health Pr	oduct Role	Dosa	ge Form	Route Administr		Dose	F	requency	Therapy Duration	Indication	n(s)
EPIPEN		Sus	spect		UTION IUSCULAR	Unknov	wn			Once			
Adverse Reaction Information	Term					_							
	Adv	erse Reac	tion Term(s)			Me	edDRA	Version			Reaction Duration		
Accidental exposur	re to produc	t by child					v.20						
Injury							v.20	0.0					

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 Report(s)

Report Informatio	n	**AE	R = Adverse R	eaction Re	port							
Adverse Reaction Report Number		R Version nber	Initial Recei	ved Date	Latest Rece	eived Date	Sourc	e of Report	Autho	arket orization ER Number	Type of Report	Reporter Type
000580630		0	2013-12	2-27	2013-1	2-27		MAH	2013	327987	Spontaneous	Physician
Serious re	eport?				Death:			Disabilit	y:		Congenital	Anomaly:
Yes			L	ife Threate	ening:		Н	ospitalizatio	n:	Other Med	dically Important Co	onditions: Yes
Patient Information	on											
Age	Gender		Height	V	Veight		Report	Outcome				
4 Years	Male					F	Recover	ed/resolved				
Link / Duplicate R	eport Infor	mation										
	Record	d Type				Link AER*	* Numb	er				
Duplicate						00057	9796					
Product Informati	on											
Product Descr	ription	Health Pr	oduct Role	Dosag	e Form	Route Administr		Dose	Fre	equency	Therapy Duration	Indication(s)
EPIPEN		Sus	spect		JTION JSCULAR	Unknov	vn					
Adverse Reaction Information	Term											
	Adv	erse Reac	tion Term(s)			Me	dDRA	Version			Reaction Duration	

v.20.0 v.20.0

Accidental exposure to product by child

Injury

Canada Vigilance Summary of Reported Adverse Reactions

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 Report(s)

Report Informatio	n	**AE	R = Adverse F	Reaction Re	eport								
Adverse Reaction Report Number		R Version	Initial Recei	ived Date	Latest Rece	ived Date	Sourc	e of Report	Auth	larket orization AER Number	Type of Report	Reporter	Туре
000583017		1	2014-0	1-17	2014-0	1-30		MAH	2014	4001951	Spontaneous	Other He Professi	
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	١	Weight		Report	Outcome					
2 Years	Unknown					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	on(s)
EPIPEN		Sus	spect		UTION USCULAR	Unknov	wn					Product for unkr indicat	nown
Adverse Reaction Information	Term												
	Adv	verse Reac	tion Term(s)			Me	dDRA	Version			Reaction Duration		
Foreign body							v.20	.0					

v.20.0

v.20.0

Injection site injury

Product quality issue

Canada Vigilance Summary of Reported Adverse Reactions

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 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
000584907	0	2014-01-24	2014-01-24	MAH	2014S1000389	Spontaneous	Consumer Or Other Non Health Professional

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

Patient Information	ation
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Age	Gender	Height	Weight	Report Outcome
2 Years	Female			Recovered/resolved

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)
EPIPEN	Suspect	SOLUTION INTRAMUSCULAR	Unknown				Product used for unknown indication

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Foreign body	v.20.0	
Injection site injury	v.20.0	
Needle issue	v.20.0	

Canada Vigilance Summary of Reported Adverse Reactions

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 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
000588647	0	2014-02-12	2014-02-12	MAH	2014S1002167	Spontaneous	Consumer Or Other Non Health Professional

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Unknown			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)
EPIPEN 0.3MG/0.3ML AUTO-INJECTOR	Suspect	SOLUTION INTRAMUSCULAR	Unknown				Product used for unknown indication

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Complication of device insertion	v.20.0	

Canada Vigilance Summary of Reported Adverse Reactions

Report Runtime: Initial Received Date: Latest Received Date: Total Number of Reports: 2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 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
000602545	0	2014-04-21	2014-04-21	MAH	2014S1008463	Spontaneous	Consumer Or Other Non Health Professional

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

Patient Information

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

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

Product Information

1 Toddot Illioniation			Route of				
Product Description	Health Product Role	Dosage Form	Administration	Dose	Frequency	Therapy Duration	Indication(s)
EPIPEN	Suspect	SOLUTION INTRAMUSCULAR	Unknown				Product used for unknown indication

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Device failure	v.20.0	
Injection site bruising	v.20.0	
Injection site pain	v.20.0	

Canada Vigilance Summary of Reported Adverse Reactions

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 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
000612250	0	2014-06-11	2014-06-11	MAH	2014S1012634	Spontaneous	Consumer Or Other Non Health Professional

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

Patient Information

Age Gender		Height	Weight	Report Outcome
	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)
EPIPEN	Suspect	SOLUTION INTRAMUSCULAR	Unknown				Hypersensitivity

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Device failure	v.20.0	

Report Runtime: Initial Received Date: Latest Received Date: Total Number of Reports: 2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 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
000614214	0	2014-06-19	2014-06-19	МАН	2014S1013632	Spontaneous	Consumer Or Other Non Health Professional

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

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

Link / Duplicate Report Information

Record Type	Link AER** Number

No duplicate or linked report.

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
EPIPEN 0.3MG/0.3ML AUTO-INJECTOR	Suspect	SOLUTION INTRAMUSCULAR	Unknown				Product used for unknown indication

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Accidental exposure to product by child	v.20.0	

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 Report(s)

Report Informa	tio	n		
Adverse Reaction Repo Number	Latest			
000616350				
Serious report?				
Yes				
Patient Informa	tio	n		
Age		Gend		
30 Years		Mal		
Link / Duplicate	R	eport I		
•				
		<u>Re</u>		

n	**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
000616350	1	2014-07-03	2014-07-18	MAH	2014S1015101	Spontaneous	Pharmacist

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

Patient Informa	tion			
Age Gender		Height	Weight	Report Outcome
30 Years	Male			Recovered/resolved

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

Product I	nform	ation

i roddot iirioriiiddioir	add information									
Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)			
EPIPEN	Suspect	SOLUTION INTRAMUSCULAR	Unknown		Once		Anaphylactic reaction			

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.20.0	
Drug dispensing error	v.20.0	
Drug ineffective	v.20.0	
Wrong technique in product usage process	v.20.0	

Report Runtime: Initial Received Date: Latest Received Date: Total Number of Reports: 2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 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
000619441	0	2014-08-04	2014-08-04	Hospital		Spontaneous	Pharmacist

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
45 Years	Male			Death

Link / Duplicate Report Information

Record Type Link AER** Number

No duplicate or linked report.

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
EPIPEN 0.3MG/0.3ML AUTO-INJECTOR	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.3 Milligram	Once		Anaphylaxis prophylaxis

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration					
Agitation	v.20.0						
Arrhythmia	v.20.0						
Brain oedema	v.20.0						
Confusional state	v.20.0						
Delirium tremens	v.20.0						
Depressed level of consciousness	v.20.0						
Dyspnoea	v.20.0						
Endotracheal intubation	v.20.0						

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Haemorrhage intracranial	v.20.0	
Headache	v.20.0	
Labile hypertension	v.20.0	
Malignant hypertension	v.20.0	

Report Runtime: Initial Received Date: Latest Received Date: Total Number of Reports: 2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 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
000620957	1	2014-07-30	2014-08-25	MAH	2014S1017260	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
	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)
EPIPEN 0.3MG/0.3ML AUTO-INJECTOR	Suspect	SOLUTION INTRAMUSCULAR	Unknown				Anaphylactic shock

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Device failure	v.20.0	
Needle issue	v.20.0	

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 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
000622138	0	2014-08-21	2014-08-21	MAH	2014S1017901	Spontaneous	Pharmacist

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
43 Years	Male	180 Centimetres	170 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)
EPIPEN 0.3MG/0.3ML AUTO-INJECTOR	Suspect	SOLUTION INTRAMUSCULAR	Unknown				Hypersensitivity

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Device failure	v.20.0	

Canada Vigilance Summary of Reported Adverse Reactions

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 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
000625554	0	2014-08-27	2014-08-27	МАН	2014M1001935	Spontaneous	Consumer Or Other Non Health Professional

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male			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	11000		Therapy Duration	Indication(s)
EPIPEN	Suspect	SOLUTION INTRAMUSCULAR	Unknown				Hypersensitivity

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Expired product administered	v.20.0	
Feeling abnormal	v.20.0	

Canada Vigilance Summary of Reported Adverse Reactions

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 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
000636913	0	2014-10-28	2014-10-28	MAH	2014M1008084	Spontaneous	Consumer Or Other Non Health Professional

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

Patient Information

- 4						
Age	Gender	Height	Weight	Report Outcome		
	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)
EPIPEN 0.3MG/0.3ML AUTO-INJECTOR	Suspect	SOLUTION INTRAMUSCULAR	Unknown		Once		Allergy to arthropod sting

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Device failure	v.20.0	

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 Report(s)

Product used

for unknown

indication

Report Information	on	**AE	R = Adverse Re	eaction Re	eport								
Adverse Reaction Report Number		R Version nber	Initial Receiv	red Date	Date Latest Received Date Source of Rep		e of Report	Market Authorization Holder AER Number		Type of Report	Reporter	Туре	
000636914		0	2014-10	-28	2014-1	0-28		MAH 2014M1008081		M1008081	Spontaneous	Consume Other Non I Profession	Health
Serious r	Serious report?			ı	Death:		Disability:			Congenital Anomaly:			
Yes	5		Li	fe Threat	ening:	g: Hospitalization:		n:	Other Medically Important Conditions:		Yes		
Patient Information	on												
Age	Gender		Height	V	Veight	Report Outcome							
	Unknown					R	ecovere	ed/resolved					
Link / Duplicate F	Report Infor	rmation											
Record Type			Link AER** Number										
No duplicate or linked report.													
Product Informat	ion												
Product Desc	ription	Health Pr	oduct Role	Dosag	je Form	Route o		Dose	Fr	equency	Therapy Duration	Indication	on(s)

Adverse Reaction	Term
Information	

EPIPEN JR 0.15MG/0.3ML

AUTO-INJECTOR

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Accidental exposure to product by child	v.20.0	
Injury associated with device	v.20.0	

Unknown

SOLUTION INTRAMUSCULAR

Suspect

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 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
000647176	4	2015-01-07	2015-06-08	MAH	2014M1016138	Spontaneous	Physician

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

Patient	Information	n

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

Link / Duplicate Report Information

Record Type	Link AER** Number

No duplicate or linked report.

Product Information

i roddot iiiioriiiddioii							
Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
EPIPEN 0.3MG/0.3ML AUTO-INJECTOR	Suspect	SOLUTION INTRAMUSCULAR	Unknown	2.0 Dermatologi cal Preparation			Hypersensitivity
EPIPEN JR 0.15MG/0.3ML AUTO-INJECTOR	Suspect	SOLUTION INTRAMUSCULAR	Unknown		Once		Hypersensitivity

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Device failure	v.20.0	
Hypersensitivity	v.20.0	
Injection site injury	v.20.0	
Scar	v.20.0	

Canada Vigilance Summary of Reported Adverse Reactions

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 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
000649353	1	2015-04-08	2015-06-04	MAH	2015M1008934	Spontaneous	Consumer Or Other Non Health Professional

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
46 Years	Male			Death

Link / Duplicate Report Information

Record Type Link AER** Number

No duplicate or linked report.

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
EPIPEN 0.3MG/0.3ML AUTO-INJECTOR	Suspect	SOLUTION INTRAMUSCULAR	Unknown		Once		Hypersensitivity

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Expired product administered	v.20.0	

Canada Vigilance Summary of Reported Adverse Reactions

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 Report(s)

Report Information

**AER = Adverse Reaction Report

Adverse Reaction Report Number	tion Report Latest AER Version Initial Received Date		Latest Received Date	test Received Date Source of Report		Type of Report	Reporter Type
000655093	0	2015-05-28	2015-05-28	MAH	2015M1016279	Spontaneous	Consumer Or Other Non Health Professional

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

Patient Information

· acronic inno				
Age	Gender	Gender Height Weight		Report Outcome
	Male			Not recovered/not resolved

Link / Duplicate Report Information

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)
EPIPEN	Suspect	SOLUTION INTRAMUSCULAR	Unknown		Once		Product used for unknown indication

Link AER Number**

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Drug ineffective	v.20.0	

Canada Vigilance Summary of Reported Adverse Reactions

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 Report(s)

Report Information

**AER = Adverse Reaction Report

Adverse Reaction Report Number	Report Latest AER Version Initial Received Date		Latest Received Date		Market Authorization Holder AER Number	Type of Report	Reporter Type
000656974	0	2015-06-15	2015-06-15	MAH	2015M1019762	Spontaneous	Consumer Or Other Non Health Professional

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Death

Link / Duplicate Report Information

Record Type

Link AER** Number

No duplicate or linked report.

Product Information

Product Description	Health Product Role	ealth Product Role Dosage Form		Dose	Frequency	Therapy Duration	Indication(s)
EPIPEN 0.3MG/0.3ML AUTO-INJECTOR	Suspect	SOLUTION INTRAMUSCULAR	Unknown		Once		

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Drug ineffective	v.20.0	

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 Report(s)

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 Recei	ved Date	Latest Rece	eived Date Sourc		e of Report	Market Authorization Holder AER Number		Type of Report	Reporter	Туре
000657096	96 0 2015-05-27 2015-0			05-27		MAH	2015N	11016748	Spontaneous	Pharma	cist		
Serious r	eport?				Death:			Disabilit	:y:		Congenital	Anomaly:	
Yes	;		L	ife Threat	ening:		H	ospitalizatio	n:	Other Med	dically Important Co	onditions:	Yes
Patient Information	on												
Age	Gender		Height	V	Veight		Report	Outcome					
62 Years	Male					F	Recovered/resolved						
Link / Duplicate R	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	Fre	equency	Therapy Duration	Indication	on(s)
	EPIPEN 0.3MG/0.3ML AUTO-INJECTOR Suspec		spect		SOLUTION RAMUSCULAR Unknown				1.0 Day(s)	Hypersen	sitivity		
Adverse Reaction Information	n Term												
	Ad	verse Reac	tion Term(s)			Me	edDRA	Version			Reaction Duration		
Device failure							v.20	.0					

Canada Vigilance Summary of Reported Adverse Reactions

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 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
000660418	0	2015-07-28	2015-07-28	MAH	2015M1024414	Spontaneous	Consumer Or Other Non Health Professional

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

Patient Information

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

Link / Duplicate Report Information

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)
EPIPEN	Suspect	SOLUTION INTRAMUSCULAR	Parenteral				Arthropod sting

Link AER Number**

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Device failure	v.20.0	
Dyspnoea	v.20.0	
Heart rate irregular	v.20.0	

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 Report(s)

Report Information	on	**AE	R = Adverse F	Reaction Re	eport							
Adverse Reaction Report Number		R Version nber	Initial Rece	ived Date	Latest Rece	eived Date	Source	of Report	Auth	arket orization AER Number	Type of Report	Reporter Typ
000661733	(0	2015-0	8-11	2015-0	08-11	l N	1AH	2015	/1023869	Spontaneous	Pharmacist
Serious re	eport?				Death:			Disabilit	y:		Congenital	Anomaly:
Yes	i		l	ife Threat	ening:		Но	spitalizatio	n:	Other Med	dically Important C	onditions: Ye
Patient Information	on											
Age	Gender		Height	1	Neight		Report 0	Outcome				
	Female					F	Recovere	d/resolved				
Link / Duplicate R	Report Infor	mation										
	Record	d Type				Link AER*	* Numbe	r				
No duplicate or link	ked report.											
Product Informati	ion											
Product Desc	ription	Health Pr	oduct Role	Dosag	ge Form	Route Administr		Dose	Fre	equency	Therapy Duration	Indication(s
EPIPEN		Sus	spect		UTION USCULAR	Unknov	wn					Product use for unknown indication
Adverse Reaction Information	n Term											
	Adv	erse Reac	tion Term(s)			Me	edDRA V	ersion			Reaction Duration	
Injection site lacera	ation						v.20.0)				

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 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
000661773	0	2015-08-12	2015-08-12	MAH	2015M1026647	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 ationi inionia				
Age	Gender	Height	Weight	Report Outcome
	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)
EPIPEN	Suspect	SOLUTION INTRAMUSCULAR	Unknown				Product used for unknown indication

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Device failure	v.20.0	
Tremor	v.20.0	

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 Report(s)

Re	port	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
000664305	8	2015-09-03	2015-10-27	MAH	2015M1029168	Study	Physician

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
	Unknown			Recovered/resolved

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)
EPIPEN JR 0.15MG/0.3ML AUTO-INJECTOR	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular		As required		

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Accidental exposure to product by child	v.20.0	
Injury associated with device	v.20.0	

Canada Vigilance Summary of Reported Adverse Reactions

Report Runtime: Initial Received Date: Latest Received Date: Total Number of Reports: 2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 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
000664477	0	2015-09-08	2015-09-08	MAH	2015MI029077	Spontaneous	Consumer Or Other Non Health Professional

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

Patient Information	ation
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Age	Gender	Height	Weight	Report Outcome
	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)
EPIPEN	Suspect	SOLUTION INTRAMUSCULAR	Unknown				Product used for unknown indication

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Device failure	v.20.0	

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 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
000664887	0	2015-09-17	2015-09-17	MAH	2015M1028271	Study	Consumer Or Other Non Health Professional

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

Patient Information	ation
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Age	Gender	Height	Weight	Report Outcome
58 Years	Male			Not recovered/not resolved

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)
EPIPEN	Suspect		Unknown	0.3 Milligram			Anaphylactic reaction
EPIPEN	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.3 Milligram			Anaphylactic reaction

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Device failure	v.20.0	
Expired product administered	v.20.0	

Canada Vigilance Summary of Reported Adverse Reactions

Report Runtime: Initial Received Date: Latest Received Date: Total Number of Reports: 2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31

139 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
000665926	0	2015-09-30	2015-09-30	MAH	2015M1032056	Spontaneous	Consumer Or Other Non Health Professional

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

Patient Information

· austri in crimation					
Age	Age Gender Height		Weight	Report Outcome	
	Unknown			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)
EPIPEN	Suspect	SOLUTION INTRAMUSCULAR	Unknown				Product used for unknown indication

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Drug ineffective	v.20.0	

Report Runtime: Initial Received Date: Latest Received Date: Total Number of Reports: 2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 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
000683250	0	2016-07-05	2016-07-05	MAH	CA-AMLO-2016-001	Spontaneous	Consumer Or Other Non Health Professional

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

Patient Information

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Age	Gender	Height	Weight	Report Outcome
52 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)
AMLODIPINE	Suspect	TABLET	Oral	10.0 Milligram	1 every 1 Day(s)		Hypertension
BESIVANCE	Suspect	SUSPENSION OPHTHALMIC			3 every 1 Day(s)		
BETOPTIC S OPH SUS 0.25%	Suspect	SUSPENSION OPHTHALMIC			1 every 1 Day(s)		
CIALIS	Suspect	TABLET	Unknown		2 every 1 Day(s)		
EPIPEN	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular		As required		Drug hypersensitivity
NASONEX	Suspect	SPRAY, METERED DOSE	Intra-nasal	2.0 Dosage forms	1 every 1 Day(s)		
OLOPATADINE	Suspect	NOT SPECIFIED	Ophthalmic		As required		

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
RATIO-PREDNISOLONE	Suspect				2 every 1 Day(s)		
RATIO-PREDNISOLONE	Suspect				4 every 1 Day(s)	2.0 Month(s)	
RATIO-PREDNISOLONE	Suspect				3 every 1 Day(s)	2.0 Month(s)	
TEVA-PREDNISONE	Suspect	TABLET		50.0 Milligram	1 every 1 Day(s)	5.0 Day(s)	
VIGAMOX	Suspect	SOLUTION OPHTHALMIC			3 every 1 Day(s)		

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypersensitivity	v.20.0	

Report Runtime: Initial Received Date: Latest Received Date: Total Number of Reports: 2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 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
000689686	0	2016-12-15	2016-12-15	Community		Spontaneous	Pharmacist

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

Patient Information

Age	Gender Height		Weight	Report Outcome		
30 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)
EPIPEN	Suspect	SOLUTION INTRAMUSCULAR	Transplacental	0.3 Milligram			Pharyngeal oedema, Allergy to chemicals

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abortion spontaneous	v.20.0	
Foetal exposure during pregnancy	v.20.0	

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31

139 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_00572802	0	2015-12-04	2015-12-04	MAH	2015M1041416	Spontaneous	Consumer Or Other Non Health Professional

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

Patient Information

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Age	Gender	Height	Weight	Report Outcome
	Unknown			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	13060		Therapy Duration	Indication(s)
EPIPEN JR 0.15MG/0.3ML AUTO-INJECTOR	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.15 Milligram			Hypersensitivity

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.20.0	
Drug ineffective	v.20.0	
Heart rate increased	v.20.0	
Pain	v.20.0	
Pallor	v.20.0	
Respiratory rate increased	v.20.0	

Canada Vigilance

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A 139 Report(s)

Summary of Reported Adverse Reactions

Report Informati	on	**AE	R = Adverse I	Reaction Re	eport								
Adverse Reaction Report Number		ER Version mber	on Initial Received Date Latest Receive		eived Date	Sourc	e of Report	Market Report Authorization Holder AER Nu		Type of Report	Reporter	Туре	
E2B_00812932		1	2016-0	5-16	2016-0)5-19		MAH	20	16255773	Study		
Serious r	eport?			l	Death: No			Disabilit	y: No		Congenital	Anomaly:	No
Yes	s			Life Threat	ening: No		Н	lospitalizatio	n: No	Other Me	dically Important Co	onditions:	Yes
Patient Informati	on												
Age	Gender		Height	V	Veight		Report	Outcome					
	Female						Un	known					
Link / Duplicate I	Report Info	rmation								_			
	Recor	d Type				Link AER*	* Numb	er					
No duplicate or lin	ked report.												
Product Informat	tion												
Product Desc	cription	Health Pr	oduct Role	Dosag	je Form	Route Administr		Dose	F	requency	Therapy Duration	Indication	on(s)
EPIPEN JR 0.15N AUTO-INJECTOR		Sus	spect		JTION USCULAR	Unknov	wn					Product for unkr indicat	nown
Adverse Reactio Information	n Term												
	Ad	verse Reac	tion Term(s)			Me	edDRA	Version			Reaction Duration		
Drug effect incomplete					v.20	0.0							

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 Report(s)

**AER = Adverse Reaction Report

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report Authorization Holder AER Number		Type of Report	Reporter Type
E2B_00838302	0	2016-06-05	2016-06-05	MAH	2016M1022668	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	3

Patient	Inform	ation
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Age	Gender	Height	Weight	Report Outcome
	Female			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)
EPIPEN	Suspect	SOLUTION INTRAMUSCULAR				1.0 Month(s)	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Drug effect incomplete	v.20.0	

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

1 Month(s)

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 Report(s)

Report Informatio	n	**AE	R = Adverse F	Reaction Re	port									
Adverse Reaction Report Number		ER Version mber	Initial Recei	ived Date	ved Date Latest Recei		ived Date	Sourc	e of Report	Auth	Market orization AER Number	Type of Report	Reporter	Туре
E2B_00839151		1	2016-0	6-06	5 2016-06				MAH	2016279756		Spontaneous	Consume Other Non Professi	Health
Serious re	port?				Death:	No			Disabilit	y: No		Congenital	Anomaly:	No
Yes			L	ife Threat	ening:	No		Н	lospitalizatio	n: No	Other Me	dically Important C	onditions:	Yes
Patient Information	n .													
Age	Gender		Height	V	Veight			Report Outcome						
	Female		V		<u> </u>			•	ed/resolved					
Link / Duplicate R	eport Info	rmation												
		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	1	Route Administr		Dose	F	requency	Therapy Duration	Indication	on(s)
EPIPEN		Sus	spect	SOLU INTRAMU	JTION JSCUL	AR	Unknov	vn					Anaphy shoo	
Adverse Reaction Information	Term													
	Adv	verse Reac	tion Term(s)				Me	dDRA	Version			Reaction Duration		

v.20.0

Drug effect incomplete

Report Runtime: Initial Received Date: Latest Received Date: Total Number of Reports: 2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 Report(s)

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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
E2B_00850983	0	2016-06-14	2016-06-14	MAH	2016M1024479	Spontaneous	Consumer Or Other Non Health Professional

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

Patient Information

· attorit iiii oi iiia					
Age	Gender	Height	Weight	Report Outcome	
20 Years	Female			Death	

Link / Duplicate Report Information	
Record Type	Link AER** Number
Duplicate	E2B 00901172

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
EPIPEN	Suspect	SOLUTION INTRAMUSCULAR				1.0 Day(s)	Food allergy

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic shock	v.20.0	1 Day(s)
Drug ineffective	v.20.0	1 Day(s)

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 Report(s)

Canada Vigilance
Summary of Reported Adverse Reactions

Report Information	on	**AE	R = Adverse F	Reaction Re	eport										
Adverse Reaction Report Number		ER Version nber	Initial Recei	ived Date	ved Date Latest Receive		eived Date	Sourc	e of Report Auti		Market Authorization Holder AER Number		Type of Report	Reporter	Туре
E2B_01005431		1	2016-10-12 2016-11-			1-14	Clin	ical Study	20	016M ²	1043226	Study	Pharma	cist	
Serious r	eport?		Death: No					Disabilit	y: I	No		Congenital	Anomaly:	No	
Yes	S		L	ife Threat	ening:	No		Н	ospitalizatio	n: l	No	Other Medically Important Conditions:		Yes	
Patient Informati	on														
Age	Gender		Height	V	Neight			Report	Outcome						
	Female			Unknown											
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	je Forn	n	Route Administr		Dose		Free	quency	Therapy Duration	Indication	on(s)
EPIPEN		Su	spect	SOLU INTRAMI	JTION USCUL	.AR									
Adverse Reaction	n Term														
	Adv	verse Read	ction Term(s)				Me	edDRA	Version	ion Reaction Duration					
Device failure								v.20	0.0						

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 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_01012992	1	2016-10-18	2016-10-26	MAH	2016484159	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	3

Patient Information	ation
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Age	Gender	Height	Weight	Report Outcome
	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)
EPIPEN	Suspect	SOLUTION INTRAMUSCULAR	Unknown				Product used for unknown indication

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Expired product administered	v.20.0	
Throat tightness	v.20.0	

Report Runtime: Initial Received Date: Latest Received Date: Total Number of Reports: 2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 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_01017970	1	2016-10-21	2016-10-28	MAH	2016426385	Spontaneous	Pharmacist

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
35 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)
EPIPEN JR 0.15MG/0.3ML AUTO-INJECTOR	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular			1.0 Day(s)	Product used for unknown indication

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Accidental exposure to product	v.20.0	1 Day(s)
Drug hypersensitivity	v.20.0	
Palpitations	v.20.0	1 Day(s)
Product quality issue	v.20.0	1 Dav(s)

Report Runtime: Initial Received Date: Latest Received Date: Total Number of Reports: 2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 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
E2B_01095488	1	2016-12-16	2016-12-30	Clinical Study	2016M1055645	Study	Consumer Or Other Non Health Professional

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

Patient Information	ation
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Age	Gender	Height	Weight	Report Outcome
8 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)
EPIPEN JR 0.15MG/0.3ML AUTO-INJECTOR	Suspect	SOLUTION INTRAMUSCULAR					Hypersensitivity

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Device failure	v.20.0	
Drug dose omission	v.20.0	

Report Runtime: Initial Received Date: Latest Received Date: Total Number of Reports: 2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 Report(s)

Report Information

**AER = Adverse Reaction Report

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report Authorization Holder AER Numb		Type of Report	Reporter Type
E2B_01103713	0	2016-12-22	2016-12-22	MAH	2016M1057628	Spontaneous	Consumer Or Other Non Health Professional

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

Patient Information

. allone mornanon				
Age Gender		Height	Weight	Report Outcome
	Female			Recovered/resolved

Link / Duplicate Report Information	
Record Type	Link AER** Number
Linked	E2B_01114260
Duplicate	E2B_01095498

Product Information

Product Description Health Product Role		Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
EPIPEN JR 0.15MG/0.3ML AUTO-INJECTOR	Suspect	SOLUTION INTRAMUSCULAR				1.0 Day(s)	Anaphylactic reaction

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Device failure	v.20.0	-38
Ecchymosis	v.20.0	0

Report Runtime: Initial Received Date: Latest Received Date: Total Number of Reports: 2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 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_01131289	0	2017-01-13	2017-01-13	MAH	CA201701003794	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:	No

Patient Informa	tion			
Age	Gender	Height	Weight	Report Outcome
52 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)
AMLODIPINE	Suspect	TABLET	Oral	10.0 Milligram	1 every 1 Day(s)		Hypertension
BESIFLOXACIN HYDROCHLORIDE	Suspect	Eye drops	Ophthalmic		1 every 1 Day(s)		Product used for unknown indication
BETAXOLOL HYDROCHLORIDE	Suspect	Eye drops	Ophthalmic		1 every 1 Day(s)		Product used for unknown indication
CIALIS	Suspect	TABLET	Unknown		1 every 1 Day(s)		Product used for unknown indication
EPIPEN JR 0.15MG/0.3ML AUTO-INJECTOR	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Drug hypersensitivity

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
MOXIFLOXACIN HYDROCHLORIDE	Suspect	Eye drops	Ophthalmic		1 every 1 Day(s)		Product used for unknown indication
NASONEX	Suspect	SPRAY, METERED DOSE	Intra-nasal	2.0 Dosage forms	1 every 1 Day(s)		Product used for unknown indication
OLOPATADINE	Suspect	NOT SPECIFIED	T SPECIFIED Ophthalmic		Product used for unknown indication		
PREDNISOLONE	Suspect		Unknown		1 every 1 Day(s)		Product used for unknown indication
PREDNISOLONE	Suspect		Unknown		1 every 1 Day(s)		Product used for unknown indication
PREDNISOLONE	Suspect	NOT SPECIFIED	Unknown		1 every 1 Day(s)		Product used for unknown indication
PREDNISONE	Suspect	NOT SPECIFIED	Unknown	50.0 Milligram	1 every 1 Day(s)		Product used for unknown indication

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypersensitivity	v.20.0	

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31

139 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
E2B_01163200	3	2017-02-06	2017-02-28	MAH	2016593928	Spontaneous	Physician

Serious report?	Death:	No	Disability:	No	Congenital Anomaly: No	<u>ე</u>
Yes	Life Threatening:	No	Hospitalization:	No	Other Medically Important Conditions: Ye	s

Patient Information

_ !							
	Age	Gender	Height	Weight	Report Outcome		
	7 Years	Female			Not recovered/not resolved		

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)
EPIPEN JR 0.15MG/0.3ML AUTO-INJECTOR	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular		As required		Food allergy

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Injection site injury	v.20.0	0
Injection site pain	v.20.0	
Needle issue	v.20.0	0
Skeletal injury	v.20.0	0

Canada Vigilanaa

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 Report(s)

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 Receiv	ved Date	te Latest Receiv		Latest Received Date		ved Date Source of		e of Report	Market Authorization Holder AER Number		Type of Report	Reporter	Туре
E2B_01176862	E2B_01176862 1 2017-02-15 2017-03				3-01	Clin	ical Study	201	7M1008725	Study	Physici	ian				
Serious re														Congenital dically Important C		
Patient Information						,						<u>, </u>				
Age	Gender		Height	V	Veight			Report	Outcome		4					
	Female							Unl	known							
Link / Duplicate R	Report Info	rmation									_					
	Recor	d Type				ı	Link AER*	* Numb	er							
No duplicate or line	ked report.															
Product Informat	ion															
Product Desc	ription	Health Pr	oduct Role	Dosag	e Form		Route Administr		Dose	F	requency	Therapy Duration	Indication	on(s)		
EPIPEN JR 0.15M AUTO-INJECTOR		Sus	spect	SOLU INTRAMU	JTION JSCULA	.R							Anaphyl shoc			
Adverse Reaction Information	n Term															
	Ad	verse Reac	tion Term(s)				Me	dDRA	Version			Reaction Duration				
Drug ineffective								v.20	0.0							

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 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_01177282	0	2017-02-16	2017-02-16	MAH	ALCN2017CA001343	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						
Α	Condon					

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

Link / Duplicate Report Information	
Record Type	Link AER** Number
Linked	E2B_01177701
Linked	

1 Todact information							
Product Description Health Product Role		Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AMLODIPINE	Suspect	TABLET	Unknown	10.0 Milligram	1 every 1 Day(s)		Hypertension
BESIFLOXACIN HYDROCHLORIDE	Suspect		Ophthalmic		3 every 1 Day(s)		Product used for unknown indication
BETAXOLOL HYDROCHLORIDE	Suspect		Ophthalmic		1 every 1 Day(s)		Product used for unknown indication
CIALIS	Suspect	TABLET	Ophthalmic				Product used for unknown indication
EPIPEN JR 0.15MG/0.3ML AUTO-INJECTOR	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Drug hypersensitivity

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
NASONEX	Suspect	SPRAY, METERED DOSE	Endosinusial		1 every 1 Day(s)		Product used for unknown indication
OLOPATADINE HYDROCHLORIDE	Suspect		Ophthalmic				Product used for unknown indication
PREDNISOLONE ACETATE	Suspect		Unknown		4 every 1 Day(s)		Product used for unknown indication
PREDNISOLONE ACETATE	Suspect		Unknown		3 every 1 Day(s)		Product used for unknown indication
PREDNISOLONE ACETATE	Suspect		Unknown		2 every 1 Day(s)		Product used for unknown indication
PREDNISONE	Suspect		Ophthalmic	50.0 Milligram	3 every 1 Day(s)		Product used for unknown indication
VIGAMOX	Suspect	SOLUTION OPHTHALMIC	Ophthalmic		3 every 1 Day(s)		Product used for unknown indication

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypersensitivity	v.20.0	

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 Report(s)

Report Information

**AER = Adverse Reaction Report

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date		Market Source of Report Authorization Holder AER Number		Reporter Type
E2B_01177701	0	2017-02-16	2017-02-16	MAH	ALCN2017CA001343	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 Informa	tion			
Age	Gender	Height Weight		Report Outcome
52 Years	Male			Recovered/resolved

Link / Duplicate Report Information	
Record Type	Link AER** Number
Linked	
Duplicate	E2B_01177282

Product Information							
Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
AMLODIPINE	Suspect	TABLET	Unknown	10.0 Milligram	1 every 1 Day(s)		Hypertension
BESIFLOXACIN HYDROCHLORIDE	Suspect		Ophthalmic		3 every 1 Day(s)		Product used for unknown indication
BETAXOLOL HYDROCHLORIDE	Suspect		Ophthalmic		1 every 1 Day(s)		Product used for unknown indication
CIALIS	Suspect	TABLET	Ophthalmic				Product used for unknown indication
EPIPEN JR 0.15MG/0.3ML AUTO-INJECTOR	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				Drug hypersensitivity

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
NASONEX	Suspect	SPRAY, METERED DOSE	Endosinusial		1 every 1 Day(s)		Product used for unknown indication
OLOPATADINE HYDROCHLORIDE	Suspect		Ophthalmic				Product used for unknown indication
PREDNISOLONE ACETATE	Suspect	Suspect			4 every 1 Day(s)		Product used for unknown indication
PREDNISOLONE ACETATE	Suspect		Unknown		3 every 1 Day(s)		Product used for unknown indication
PREDNISOLONE ACETATE	Suspect		Unknown		2 every 1 Day(s)		Product used for unknown indication
PREDNISONE	Suspect		Ophthalmic	50.0 Milligram	3 every 1 Day(s)		Product used for unknown indication
VIGAMOX	Suspect	SOLUTION OPHTHALMIC	Ophthalmic		3 every 1 Day(s)		Product used for unknown indication

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypersensitivity	v.20.0	

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 Report(s)

Report Information	on	**AE	R = Adverse R	Reaction Re	eport								
Adverse Reaction Report Number		ER Version mber	Initial Recei	ved Date	Latest Red	eived Date	Sourc	ource of Report		Market norization AER Number	Type of Report	Reporter	Туре
E2B_01178400		1	2017-02	2-16	2017	-03-01	Clin	ical Study	2017	M1008730	Study	Physici	ian
Serious report?				ı	Death: No			Disabilit			Congenital		
Yes	3		L	ife Threat	ening: Yes		Н	ospitalizatio	n: No	Other Med	dically Important Co	onditions:	Yes
Patient Information	on					_				-			
Age	Gender		Height	V	Weight Report Outcome								
10 Years	Male				Unknown								
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	F	requency	Therapy Duration	Indication	on(s)
EPIPEN JR 0.15M AUTO-INJECTOR		Sus	spect		JTION USCULAR							Anaphyl shoc	
Adverse Reaction Information	n Term												
	Ad	verse Reac	tion Term(s)			Me	MedDRA Version				Reaction Duration		
Drug ineffective							v.20	0.0					

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 Report(s)

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 Recei	ived Date	Lates	st Rece	eived Date	Sourc	e of Report	_	Autho	arket orization ER Number	Type of Report	Reporter	Туре
E2B_01220494		2	2017-0	2017-03-16 2017-03-)3-31		MAH		2017	083336	Spontaneous	Pharma	acist
Serious re	eport?		Death: No				Disability: No				Congenital	Anomaly:	No		
Yes	Yes Life Threatening: Yes				Н	ospitalizatio	n:	No	Other Med	dically Important Co	onditions:	Yes			
Patient Information	on														
Age	Gender		Height	1	Weight			Report	Outcome						
42 Years	Female				3			Recovered/resolved							
Link / Duplicate R	Report Info	rmation													
	Recor	d Type					Link AER*	* Numb	er						
No duplicate or line	ked report.														
Product Informati	ion														
Product Desc	ription	Health Pr	oduct Role	Dosag	ge Forn	n	Route Administr		Dose		Fre	quency	Therapy Duration	Indicati	on(s)
EPIPEN JR 0.15M AUTO-INJECTOR		Su	spect	SOLI INTRAM	UTION USCUL	.AR	Unknov	wn	0.3 Milligra	m	As	required		Hyperser	nsitivity
Adverse Reaction Information	n Term														
	Ad	verse Read	tion Term(s)				Me	edDRA	Version				Reaction Duration		
Device issue								v.20	0.0						
Product quality iss	ue							v.20	0.0						

Underdose

v.20.0

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 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_01229377	0	2017-03-23	2017-03-23	MAH	2017120389	Published	

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

Patient Information

Age	Age Gender		Weight	Report Outcome		
9 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)
EPIPEN JR 0.15MG/0.3ML AUTO-INJECTOR	Suspect	SOLUTION INTRAMUSCULAR	Unknown	0.3 Milligram			Product used for unknown indication

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Accidental exposure to product by child	v.20.0	
Injection site coldness	v.20.0	
Injection site ischaemia	v.20.0	
Injection site pain	v.20.0	
Injection site pallor	v.20.0	
Injection site paraesthesia	v.20.0	

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

2017-09-09 - 08:12:46 PM 1965-01-01 to 2017-03-31 N/A

139 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_01240046	0	2017-03-29	2017-03-29	MAH	2017M1019016	Spontaneous	Consumer Or Other Non Health Professional

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

Patient Information

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

Link / Duplicate Report Information

Record Type

Record Type Link AER** Number

No duplicate or linked report.

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
EPIPEN JR 0.15MG/0.3ML AUTO-INJECTOR	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular			1.0 Month(s)	Anaphylactic reaction

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Device failure	v.20.0	1 Month(s)