Health Canada Santé Canada

Canada Vigilance
Summary of Reported Adverse Reactions

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

Canada

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Report Information

***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
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 Information

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	

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Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
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 Information

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

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

Adverse Reaction Term Information

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

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Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
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

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 Information

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

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Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000160990	0	2003-05-15	2003-05-15	MAH	0210393	Spontaneous	Physician

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
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 Information

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

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Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
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 Information

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

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 Information

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

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Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
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 Information

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.	

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			

Adverse Reaction Term Information

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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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
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 Information

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

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

Adverse Reaction Term Information

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

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Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
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

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

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

Adverse Reaction Term Information

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

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Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
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 Information

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

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Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000165859	0	2003-11-17	2003-11-17	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
58 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	0.3 Milligram			

Adverse Reaction Term Information

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

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Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
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

Patient Information

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 Information

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

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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 Information

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

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 Information

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

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Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
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 Information

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 Information

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

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Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000169115	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 Information

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	

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000169139	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
18 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 Information

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

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000169643	0	2004-04-02	2004-04-02	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
8 Years	Male			Unknown

Link / Duplicate Report Information

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

Product Information

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

Adverse Reaction Term Information

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

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000169658	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

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 Information

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

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000172240	0	2004-06-29	2004-06-29	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
4 Years	Male			Recovered/resolved

Link / Duplicate Report Information

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

Product Information

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

Adverse Reaction Term Information

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

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000172485	0	2004-07-09	2004-07-09	Community		Spontaneous	Pharmacist

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
26 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 Information

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

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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
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 Information

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

Age	Gender	Height	Weight	Report Outcome
5 Years	Female			Unknown

Link / Duplicate Report Information

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

Product Information

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

Adverse Reaction Term Information

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: 2017-09-09 - 08:12:46 PM
Initial Received Date: 1965-01-01 to 2017-03-31
Latest Received Date: N/A
Total Number of Reports: 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
000173840	0	2004-08-23	2004-08-23	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
16 Years	Male			Unknown

Link / Duplicate Report Information

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

Product Information

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

Adverse Reaction Term Information

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

Canada Vigilance
Summary of Reported Adverse Reactions

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

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 Information

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	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2017-09-09 - 08:12:46 PM
Initial Received Date: 1965-01-01 to 2017-03-31
Latest Received Date: N/A
Total Number of Reports: 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
000174495	0	2004-09-14	2005-01-18	Community		Spontaneous	Physician

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
28 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 Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypoaesthesia	v.20.0	
Nerve injury	v.20.0	

Canada Vigilance
Summary of Reported Adverse Reactions

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

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

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

Adverse Reaction Term Information

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: 2017-09-09 - 08:12:46 PM
Initial Received Date: 1965-01-01 to 2017-03-31
Latest Received Date: N/A
Total Number of Reports: 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
000175241	0	2004-10-04	2004-10-04	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
	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)
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 Information

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	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2017-09-09 - 08:12:46 PM
Initial Received Date: 1965-01-01 to 2017-03-31
Latest Received Date: N/A
Total Number of Reports: 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
000176279	0	2004-10-29	2004-10-29	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			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 Information

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	

Canada Vigilance
Summary of Reported Adverse Reactions

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

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	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2017-09-09 - 08:12:46 PM
Initial Received Date: 1965-01-01 to 2017-03-31
Latest Received Date: N/A
Total Number of Reports: 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
000176977	0	2004-11-15	2004-11-15	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
13 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			
NITROGLYCERIN PASTE	Drug used to treat AE	NOT SPECIFIED					

Adverse Reaction Term Information

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: 2017-09-09 - 08:12:46 PM
Initial Received Date: 1965-01-01 to 2017-03-31
Latest Received Date: N/A
Total Number of Reports: 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
000179932	0	1997-04-28	1997-04-28	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
17 Years	Female	163 Centimetres	54 Kilograms	Not recovered/not resolved

Link / Duplicate Report Information

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

Product Information

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

Adverse Reaction Term Information

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

Canada Vigilance
Summary of Reported Adverse Reactions

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

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

Adverse Reaction Term Information

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

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 Information

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

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 Information

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

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 Information

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

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

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

Adverse Reaction Term Information

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

Canada Vigilance
Summary of Reported Adverse Reactions

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

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:	2017-09-09 - 08:12:46 PM
Initial Received Date:	1965-01-01 to 2017-03-31
Latest Received Date:	N/A
Total Number of Reports:	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
000192562	0	2005-10-27	2005-10-27	Community		Spontaneous	Other Health Professional

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
11 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 JR	Suspect	SOLUTION INTRAMUSCULAR	Unknown				

Adverse Reaction Term Information

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

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2017-09-09 - 08:12:46 PM
Initial Received Date: 1965-01-01 to 2017-03-31
Latest Received Date: N/A
Total Number of Reports: 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
000192564	0	2005-10-27	2005-10-27	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
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 Information

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

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2017-09-09 - 08:12:46 PM
Initial Received Date: 1965-01-01 to 2017-03-31
Latest Received Date: N/A
Total Number of Reports: 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
000194330	0	2005-12-09	2005-12-09	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
62 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	Unknown	0.3 mL			

Adverse Reaction Term Information

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	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2017-09-09 - 08:12:46 PM
Initial Received Date: 1965-01-01 to 2017-03-31
Latest Received Date: N/A
Total Number of Reports: 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
000194334	0	2005-12-09	2005-12-09	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	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	Unknown				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cardiovascular disorder	v.20.0	
Skin discolouration	v.20.0	

Canada Vigilance
Summary of Reported Adverse Reactions

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

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	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2017-09-09 - 08:12:46 PM
Initial Received Date: 1965-01-01 to 2017-03-31
Latest Received Date: N/A
Total Number of Reports: 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
000196837	0	2006-02-02	2006-02-02	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
11 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				

Adverse Reaction Term Information

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

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2017-09-09 - 08:12:46 PM
Initial Received Date: 1965-01-01 to 2017-03-31
Latest Received Date: N/A
Total Number of Reports: 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
000201734	0	2006-05-03	2006-05-03	MAH		Spontaneous	Physician

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
44 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	Intramuscular				
TYLENOL EXTRA STRENGTH TAB 500MG	Drug used to treat AE	TABLET	Unknown				

Adverse Reaction Term Information

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

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2017-09-09 - 08:12:46 PM
Initial Received Date: 1965-01-01 to 2017-03-31
Latest Received Date: N/A
Total Number of Reports: 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
000202182	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
	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				
PHENTOLAMINE	Drug used to treat AE	NOT SPECIFIED	Unknown				

Adverse Reaction Term Information

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

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2017-09-09 - 08:12:46 PM
Initial Received Date: 1965-01-01 to 2017-03-31
Latest Received Date: N/A
Total Number of Reports: 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
000202190	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

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 Information

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	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2017-09-09 - 08:12:46 PM
Initial Received Date: 1965-01-01 to 2017-03-31
Latest Received Date: N/A
Total Number of Reports: 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
000202196	0	2006-05-15	2006-05-15	MAH		Spontaneous	Pharmacist

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
37 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	Unknown	0.5 Milligram	Once		

Adverse Reaction Term Information

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

Canada Vigilance
Summary of Reported Adverse Reactions

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

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 Information

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	

Canada Vigilance
Summary of Reported Adverse Reactions

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

Adverse Reaction Term Information

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	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2017-09-09 - 08:12:46 PM
Initial Received Date: 1965-01-01 to 2017-03-31
Latest Received Date: N/A
Total Number of Reports: 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
000216589	0	2007-03-16	2007-03-16	MAH	K200700286	Spontaneous	Physician

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

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

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

Adverse Reaction Term Information

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

Canada Vigilance
Summary of Reported Adverse Reactions

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

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 Information

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

Canada Vigilance
Summary of Reported Adverse Reactions

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

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 Information

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	

Canada Vigilance
Summary of Reported Adverse Reactions

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

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

Canada Vigilance
Summary of Reported Adverse Reactions

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

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

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 Information

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:	2017-09-09 - 08:12:46 PM
Initial Received Date:	1965-01-01 to 2017-03-31
Latest Received Date:	N/A
Total Number of Reports:	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
000224222	0	2007-10-12	2007-10-12	MAH	K200701279	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
40 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	Intradermal	0.3 Milligram	Once		
PHENTOLAMINE	Drug used to treat AE	NOT SPECIFIED					

Adverse Reaction Term Information

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

Canada Vigilance
Summary of Reported Adverse Reactions

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

Age	Gender	Height	Weight	Report Outcome
52 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	0.3 Milligram	2 every 1 Day(s)		
TWINJECT AUTO-INJECTOR	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular				

Adverse Reaction Term Information

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	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2017-09-09 - 08:12:46 PM
Initial Received Date: 1965-01-01 to 2017-03-31
Latest Received Date: N/A
Total Number of Reports: 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
000303474	0	2008-05-15	2008-05-15	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
23 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 JR	Suspect	SOLUTION INTRAMUSCULAR	Subdermal				Product used for unknown indication

Adverse Reaction Term Information

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	

Canada Vigilance
Summary of Reported Adverse Reactions

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

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	

Canada Vigilance
Summary of Reported Adverse Reactions

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

Age	Gender	Height	Weight	Report Outcome
27 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	0.3 Milligram	Once		Rubber sensitivity
IUD NOS	Concomitant		Intra-uterine				
MORPHINE	Concomitant	NOT SPECIFIED	Unknown				

Adverse Reaction Term Information

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

Canada Vigilance
Summary of Reported Adverse Reactions

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

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 Information

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

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2017-09-09 - 08:12:46 PM
Initial Received Date:	1965-01-01 to 2017-03-31
Latest Received Date:	N/A
Total Number of Reports:	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
000313195	1	2008-10-30	2008-11-10	MAH	K200801242	Spontaneous	Lawyer

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
56 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	0.3 Milligram	Once		Product used for unknown indication

Adverse Reaction Term Information

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: 2017-09-09 - 08:12:46 PM
Initial Received Date: 1965-01-01 to 2017-03-31
Latest Received Date: N/A
Total Number of Reports: 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
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	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
EPIPEN	Suspect	SOLUTION INTRAMUSCULAR	Unknown				Anaphylactic reaction

Adverse Reaction Term Information

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

Canada Vigilance
Summary of Reported Adverse Reactions

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

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 Information

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

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

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2017-09-09 - 08:12:46 PM
Initial Received Date: 1965-01-01 to 2017-03-31
Latest Received Date: N/A
Total Number of Reports: 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
000327856	0	2009-08-03	2009-08-03	MAH	K200900904	Spontaneous	Pharmacist

Serious report?	Death:		Disability:		Congenital Anomaly:	
No	Life Threatening:		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	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
EPIPEN	Suspect	SOLUTION INTRAMUSCULAR	Unknown	0.3 Milligram			Anaphylactic reaction

Adverse Reaction Term Information

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

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2017-09-09 - 08:12:46 PM
Initial Received Date: 1965-01-01 to 2017-03-31
Latest Received Date: N/A
Total Number of Reports: 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
000327871	1	2009-08-03	2009-10-16	MAH	K200900878	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
52 Years	Female			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Duplicate	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 Information

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

Canada Vigilance
Summary of Reported Adverse Reactions

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

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	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	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2017-09-09 - 08:12:46 PM
Initial Received Date: 1965-01-01 to 2017-03-31
Latest Received Date: N/A
Total Number of Reports: 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
000346444	1	2010-06-28	2010-07-22	MAH	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
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 Information

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	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2017-09-09 - 08:12:46 PM
Initial Received Date: 1965-01-01 to 2017-03-31
Latest Received Date: N/A
Total Number of Reports: 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
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 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	Suspect	SOLUTION INTRAMUSCULAR	Parenteral				Product used for unknown indication

Adverse Reaction Term Information

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	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2017-09-09 - 08:12:46 PM
Initial Received Date: 1965-01-01 to 2017-03-31
Latest Received Date: N/A
Total Number of Reports: 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
000385172	0	2011-11-08	2011-11-08	MAH	K201101052	Spontaneous	Pharmacist

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Male			Death

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
EPIPEN	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.9 Milligram	Total		Anaphylactic reaction

Adverse Reaction Term Information

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

Canada Vigilance
Summary of Reported Adverse Reactions

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

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
51 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	Parenteral	0.3 Milligram	As required		Anaphylactic reaction

Adverse Reaction Term Information

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

Canada Vigilance
Summary of Reported Adverse Reactions

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

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

Canada Vigilance
Summary of Reported Adverse Reactions

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

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	

Canada Vigilance
Summary of Reported Adverse Reactions

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

Age	Gender	Height	Weight	Report Outcome
15 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				Anaphylactic reaction

Adverse Reaction Term Information

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	

Canada Vigilance
Summary of Reported Adverse Reactions

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

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 Information

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	

Canada Vigilance
Summary of Reported Adverse Reactions

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

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

Link / Duplicate Report Information

Record Type	Link AER** 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 Information

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

Canada Vigilance
Summary of Reported Adverse Reactions

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

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	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 Information

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

Canada Vigilance
Summary of Reported Adverse Reactions

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

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	

Canada Vigilance
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Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
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

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 Information

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

Canada Vigilance
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Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
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

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 Information

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

Canada Vigilance
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Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000540440	0	2013-07-11	2013-07-11	MAH	2013199164	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			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				Arthropod sting

Adverse Reaction Term Information

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

Canada Vigilance
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Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
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:	

Patient Information

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

Link / Duplicate Report Information

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

Product Information

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

Adverse Reaction Term Information

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

Canada Vigilance
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Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
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	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				Hypersensitivity

Adverse Reaction Term Information

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

Canada Vigilance
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Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
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

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 Information

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	

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000566062	0	2013-10-24	2013-10-24	MAH	2013297594	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
	Unknown			Unknown

Link / Duplicate Report Information

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

Product Information

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

Adverse Reaction Term Information

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

Canada Vigilance
Summary of Reported Adverse Reactions

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Report Information

***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
000573362	0	2013-11-22	2013-11-22	MAH	2013S1025342	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
58 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)
CRESTOR	Concomitant	TABLET					
EPIPEN	Suspect	SOLUTION INTRAMUSCULAR	Unknown				Allergy to arthropod bite

Adverse Reaction Term Information

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

Canada Vigilance
Summary of Reported Adverse Reactions

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Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
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 Information

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
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Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
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 Information

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
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Report Information ***AER = Adverse Reaction Report*

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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

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 Information

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

Canada Vigilance
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Report Information ***AER = Adverse Reaction Report*

Adverse Reaction Report Number	Latest AER Version Number	Initial Received Date	Latest Received Date	Source of Report	Market Authorization Holder AER Number	Type of Report	Reporter Type
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

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 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 Information

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

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000579796	0	2013-12-20	2013-12-20	MAH	2013S1026126	Spontaneous	Physician

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

Patient Information

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

Link / Duplicate Report Information

Record Type	Link AER** Number
Duplicate	000580630

Product Information

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

Adverse Reaction Term Information

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

Canada Vigilance
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000580630	0	2013-12-27	2013-12-27	MAH	2013327987	Spontaneous	Physician

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

Patient Information

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

Link / Duplicate Report Information

Record Type	Link AER** Number
Duplicate	000579796

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 Information

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

Canada Vigilance
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000583017	1	2014-01-17	2014-01-30	MAH	2014001951	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
2 Years	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 Information

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

Canada Vigilance
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Report Runtime: 2017-09-09 - 08:12:46 PM
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Latest Received Date: N/A
Total Number of Reports: 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
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

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

Link / Duplicate Report Information

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

Product Information

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

Adverse Reaction Term Information

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

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

Canada Vigilance
Summary of Reported Adverse Reactions

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

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 Information

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

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

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2017-09-09 - 08:12:46 PM
Initial Received Date: 1965-01-01 to 2017-03-31
Latest Received Date: N/A
Total Number of Reports: 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
000614214	0	2014-06-19	2014-06-19	MAH	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

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 Information

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

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2017-09-09 - 08:12:46 PM
Initial Received Date: 1965-01-01 to 2017-03-31
Latest Received Date: N/A
Total Number of Reports: 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
000616350	1	2014-07-03	2014-07-18	MAH	2014S1015101	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	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		Once		Anaphylactic reaction

Adverse Reaction Term Information

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	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2017-09-09 - 08:12:46 PM
Initial Received Date: 1965-01-01 to 2017-03-31
Latest Received Date: N/A
Total Number of Reports: 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
000619441	0	2014-08-04	2014-08-04	Hospital		Spontaneous	Pharmacist

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

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	

Canada Vigilance
Summary of Reported Adverse Reactions

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

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

Canada Vigilance
Summary of Reported Adverse Reactions

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

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

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2017-09-09 - 08:12:46 PM
Initial Received Date: 1965-01-01 to 2017-03-31
Latest Received Date: N/A
Total Number of Reports: 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
000625554	0	2014-08-27	2014-08-27	MAH	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	Dose	Frequency	Therapy Duration	Indication(s)
EPIPEN	Suspect	SOLUTION INTRAMUSCULAR	Unknown				Hypersensitivity

Adverse Reaction Term Information

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

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 Information

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

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2017-09-09 - 08:12:46 PM
Initial Received Date: 1965-01-01 to 2017-03-31
Latest Received Date: N/A
Total Number of Reports: 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
000636914	0	2014-10-28	2014-10-28	MAH	2014M1008081	Spontaneous	Consumer Or Other Non Health Professional

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Unknown			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				Product used for unknown indication

Adverse Reaction Term Information

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

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

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 Dermatological Preparation			Hypersensitivity
EPIPEN JR 0.15MG/0.3ML AUTO-INJECTOR	Suspect	SOLUTION INTRAMUSCULAR	Unknown		Once		Hypersensitivity

Adverse Reaction Term Information

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

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

Canada Vigilance
Summary of Reported Adverse Reactions

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

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		Once		Product used for unknown indication

Adverse Reaction Term Information

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

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2017-09-09 - 08:12:46 PM
Initial Received Date: 1965-01-01 to 2017-03-31
Latest Received Date: N/A
Total Number of Reports: 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
000656974	0	2015-06-15	2015-06-15	MAH	2015M1019762	Spontaneous	Consumer Or Other Non Health Professional

Serious report?	Death:	Disability:	Congenital Anomaly:
Yes	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	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration	Indication(s)
EPIPEN 0.3MG/0.3ML AUTO-INJECTOR	Suspect	SOLUTION INTRAMUSCULAR	Unknown		Once		

Adverse Reaction Term Information

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

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2017-09-09 - 08:12:46 PM
Initial Received Date: 1965-01-01 to 2017-03-31
Latest Received Date: N/A
Total Number of Reports: 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
000657096	0	2015-05-27	2015-05-27	MAH	2015M1016748	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
62 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 0.3MG/0.3ML AUTO-INJECTOR	Suspect	SOLUTION INTRAMUSCULAR	Unknown			1.0 Day(s)	Hypersensitivity

Adverse Reaction Term Information

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

Canada Vigilance
Summary of Reported Adverse Reactions

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

Adverse Reaction Term Information

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

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2017-09-09 - 08:12:46 PM
Initial Received Date: 1965-01-01 to 2017-03-31
Latest Received Date: N/A
Total Number of Reports: 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
000661733	0	2015-08-11	2015-08-11	MAH	2015M1023869	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
	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 Information

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

Canada Vigilance
Summary of Reported Adverse Reactions

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

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 Information

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

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2017-09-09 - 08:12:46 PM
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Latest Received Date: N/A
Total Number of Reports: 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
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

Record Type	Link AER** 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		As required		

Adverse Reaction Term Information

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

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 Information

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

Canada Vigilance
Summary of Reported Adverse Reactions

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

Age	Gender	Height	Weight	Report Outcome
58 Years	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		Unknown	0.3 Milligram			Anaphylactic reaction
EPIPEN	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.3 Milligram			Anaphylactic reaction

Adverse Reaction Term Information

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

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 Information

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

Canada Vigilance
Summary of Reported Adverse Reactions

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

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 Information

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

Canada Vigilance
Summary of Reported Adverse Reactions

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

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

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2017-09-09 - 08:12:46 PM
Initial Received Date: 1965-01-01 to 2017-03-31
Latest Received Date: N/A
Total Number of Reports: 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
E2B_00572802	0	2015-12-04	2015-12-04	MAH	2015M1041416	Spontaneous	Consumer Or Other Non Health Professional

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

Patient Information

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 JR 0.15MG/0.3ML AUTO-INJECTOR	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular	0.15 Milligram			Hypersensitivity

Adverse Reaction Term Information

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
Summary of Reported Adverse Reactions

Report Runtime: 2017-09-09 - 08:12:46 PM
Initial Received Date: 1965-01-01 to 2017-03-31
Latest Received Date: N/A
Total Number of Reports: 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
E2B_00812932	1	2016-05-16	2016-05-19	MAH	2016255773	Study	

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
	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 JR 0.15MG/0.3ML AUTO-INJECTOR	Suspect	SOLUTION INTRAMUSCULAR	Unknown				Product used for unknown indication

Adverse Reaction Term Information

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

Canada Vigilance
Summary of Reported Adverse Reactions

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

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

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 Information

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

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2017-09-09 - 08:12:46 PM
Initial Received Date: 1965-01-01 to 2017-03-31
Latest Received Date: N/A
Total Number of Reports: 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
E2B_00839151	1	2016-06-06	2016-06-09	MAH	2016279756	Spontaneous	Consumer Or Other Non Health Professional

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
	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				Anaphylactic shock

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Drug effect incomplete	v.20.0	1 Month(s)

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2017-09-09 - 08:12:46 PM
Initial Received Date: 1965-01-01 to 2017-03-31
Latest Received Date: N/A
Total Number of Reports: 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
E2B_00850983	0	2016-06-14	2016-06-14	MAH	2016M1024479	Spontaneous	Consumer Or Other Non Health Professional

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
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 Information

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

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2017-09-09 - 08:12:46 PM
Initial Received Date: 1965-01-01 to 2017-03-31
Latest Received Date: N/A
Total Number of Reports: 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
E2B_01005431	1	2016-10-12	2016-11-14	Clinical Study	2016M1043226	Study	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
	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					

Adverse Reaction Term Information

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

Canada Vigilance
Summary of Reported Adverse Reactions

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

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

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 Information

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

Canada Vigilance
Summary of Reported Adverse Reactions

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

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 Day(s)

Canada Vigilance
Summary of Reported Adverse Reactions

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

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 Information

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

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2017-09-09 - 08:12:46 PM
Initial Received Date: 1965-01-01 to 2017-03-31
Latest Received Date: N/A
Total Number of Reports: 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
E2B_01103713	0	2016-12-22	2016-12-22	MAH	2016M1057628	Spontaneous	Consumer Or Other Non Health Professional

Serious report?	Death:	Disability:	Congenital Anomaly:
Yes	No	No	No
	Life Threatening: Yes	Hospitalization: No	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
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 Information

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

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2017-09-09 - 08:12:46 PM
Initial Received Date:	1965-01-01 to 2017-03-31
Latest Received Date:	N/A
Total Number of Reports:	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
E2B_01131289	0	2017-01-13	2017-01-13	MAH	CA201701003794	Spontaneous	Consumer Or Other Non Health Professional

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

Patient Information

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	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 Information

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

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2017-09-09 - 08:12:46 PM
Initial Received Date: 1965-01-01 to 2017-03-31
Latest Received Date: N/A
Total Number of Reports: 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
E2B_01163200	3	2017-02-06	2017-02-28	MAH	2016593928	Spontaneous	Physician

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
7 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 JR 0.15MG/0.3ML AUTO-INJECTOR	Suspect	SOLUTION INTRAMUSCULAR	Intramuscular		As required		Food allergy

Adverse Reaction Term Information

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 Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2017-09-09 - 08:12:46 PM
Initial Received Date: 1965-01-01 to 2017-03-31
Latest Received Date: N/A
Total Number of Reports: 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
E2B_01176862	1	2017-02-15	2017-03-01	Clinical Study	2017M1008725	Study	Physician

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
	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 JR 0.15MG/0.3ML AUTO-INJECTOR	Suspect	SOLUTION INTRAMUSCULAR					Anaphylactic shock

Adverse Reaction Term Information

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

Canada Vigilance
Summary of Reported Adverse Reactions

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

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

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	E2B_01177701
Linked	

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		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 Information

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

Canada Vigilance
Summary of Reported Adverse Reactions

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

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		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 Information

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

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2017-09-09 - 08:12:46 PM
Initial Received Date: 1965-01-01 to 2017-03-31
Latest Received Date: N/A
Total Number of Reports: 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
E2B_01178400	1	2017-02-16	2017-03-01	Clinical Study	2017M1008730	Study	Physician

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
10 Years	Male			Unknown

Link / Duplicate Report Information

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

Product Information

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

Adverse Reaction Term Information

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

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2017-09-09 - 08:12:46 PM
Initial Received Date: 1965-01-01 to 2017-03-31
Latest Received Date: N/A
Total Number of Reports: 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
E2B_01220494	2	2017-03-16	2017-03-31	MAH	2017083336	Spontaneous	Pharmacist

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
42 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	As required		Hypersensitivity

Adverse Reaction Term Information

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

Canada Vigilance
Summary of Reported Adverse Reactions

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

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	

Canada Vigilance
Summary of Reported Adverse Reactions

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

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