Health Canada Santé Canada

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2014-07-13 - 09:53:00 AM
Initial Received Date:	1965-01-01 to 2014-03-31
Latest Received Date:	N/A
Total Number of Reports:	562 Report(s)

Brand Name/Active Ingredient: levothyroxine
Search Date Criteria: 1965-01-01 to 2014-03-31
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

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000000690	0	1973-08-20	1973-08-20	Hospital		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
75 Years	Female	157 Centimetres	57 Kilograms	Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration
L-THYROXINE	Suspect	NOT SPECIFIED	Oral	0.1 Milligram	1 every 1 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.17.0	
Diarrhoea	v.17.0	
Tachycardia	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000001076	0	1973-10-16	1973-10-16	Hospital		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
				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
ACTIFED	Suspect	NOT SPECIFIED	Oral			
SYNTHROID	Suspect	NOT SPECIFIED	Oral			
TETRACYCLINE	Suspect	NOT SPECIFIED				
VALIUM NOS	Suspect	NOT SPECIFIED				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pruritus	v.17.0	
Urticaria	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000002864	0	1974-04-23	1974-04-23	Hospital		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
73 Years	Female	158 Centimetres	53 Kilograms	Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration
ALDACTONE	Concomitant	TABLET	Oral			
ANTIVERT TAB	Concomitant	TABLET	Oral			
INDERAL	Concomitant	NOT SPECIFIED	Oral			
L-THYROXINE	Suspect	NOT SPECIFIED	Oral	200.0 Microgram		
LANOXIN	Concomitant	NOT SPECIFIED				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Atrial fibrillation	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000008733	0	1976-01-05	1976-01-05			Spontaneous	Physician

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
ELTROXIN	Suspect	TABLET	Oral	0.2 Milligram	1 every 1 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypothyroidism	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000009102	0	1976-02-20	1976-02-20	Hospital		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
19 Years	Female	167 Centimetres	58 Kilograms	Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration
SYNTHROID	Suspect	TABLET	Oral	0.25 Milligram		5.0 Month(s)

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Nausea	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2014-07-13 - 09:53:00 AM
Initial Received Date:	1965-01-01 to 2014-03-31
Latest Received Date:	N/A
Total Number of Reports:	562 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
000009332	0	1976-03-16	1976-03-16			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	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
ELTROXIN	Suspect	TABLET	Oral	2.0 Dosage forms	1 every 1 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Periorbital oedema	v.17.0	
Urticaria	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000009419	0	1976-03-18	1976-03-18	Hospital		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
59 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
ELTROXIN	Suspect	TABLET	Oral	0.5 Milligram	1 every 1 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hyperhidrosis	v.17.0	
Supraventricular tachycardia	v.17.0	
Weight decreased	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000010296	0	1976-06-09	1976-06-09	Hospital		Spontaneous	

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
NEO-MERCAZOLE	Suspect	NOT SPECIFIED		5.0 Milligram	2 every 1 Day(s)	9.0 Month(s)
SYNTHROID	Suspect	NOT SPECIFIED	Oral	0.1 Milligram		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anal atresia	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000015187	0	1977-11-14	1977-11-14	Hospital		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
83 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
PROLOPA	Concomitant	CAPSULE	Oral	250.0 Milligram	3 every 1 Day(s)	
SYNTHROID	Suspect	NOT SPECIFIED	Oral	0.1 Milligram	1 every 1 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Urticaria	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000017829	0	1978-07-07	1978-07-07	Hospital		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
19 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
SYNTHROID	Suspect	NOT SPECIFIED	Oral	0.02 Milligram	4 every 1 Day(s)	7.0 Day(s)

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hyperthyroidism	v.17.0	
Tremor	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000018359	0	1978-03-14	1978-03-14			Spontaneous	Physician

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
62 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
ATROMID-S	Suspect	CAPSULE	Oral	2.0 Dosage forms		
SYNTHROID	Suspect	TABLET	Oral	1.0 Dosage forms		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Keratitis	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000018642	0	1978-10-06	1978-10-06	Hospital		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
62 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
INDERAL	Concomitant	NOT SPECIFIED	Oral	40.0 Milligram	4 every 1 Day(s)	
THYROXINE	Suspect	NOT SPECIFIED	Oral	200.0 Milligram	1 every 1 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.17.0	
Hyperhidrosis	v.17.0	
Ventricular tachycardia	v.17.0	
Weight decreased	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000019905	0	1979-01-31	1979-01-31			Spontaneous	Pharmacist

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
				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
ELTROXIN	Suspect	TABLET	Oral			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Therapeutic response decreased	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000020231	0	1979-03-05	1979-03-05	Hospital		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
76 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
AMITRIPTYLINE	Suspect	NOT SPECIFIED	Oral	25.0 Milligram	4 every 1 Day(s)	
DIGOXIN	Concomitant	NOT SPECIFIED	Oral	0.25 Milligram	1 every 1 Day(s)	
HYDROCHLOROTHIAZIDE	Concomitant	TABLET	Oral	50.0 Milligram	1 every 1 Day(s)	
IMODIUM - CAPLET 2MG	Concomitant	TABLET	Oral	6.0 Dosage forms	1 every 1 Day(s)	
L-THYROXINE	Suspect	NOT SPECIFIED	Oral	0.1 Milligram		40.0 Year(s)
SLOW K 600MG	Concomitant	TABLET (EXTENDED-RELEASE)	Oral	2.0 Dosage forms	3 every 1 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000020232	0	1979-03-05	1979-03-05	Hospital		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
76 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
DIGOXIN	Suspect	NOT SPECIFIED	Oral	0.25 Milligram		
L-THYROXINE	Suspect	NOT SPECIFIED	Oral	0.1 Milligram		40.0 Year(s)

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Atrioventricular block first degree	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000020236	0	1979-03-05	1979-03-05	Hospital		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
61 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
ANAFRANIL	Suspect	TABLET	Oral	25.0 Milligram	3 every 1 Day(s)	
L-THYROXINE	Suspect	NOT SPECIFIED	Oral	0.1 Milligram		14.0 Year(s)

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Vomiting	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000020825	0	1979-04-20	1979-04-20	Hospital		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
42 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
DIGOXIN	Drug used to treat AE	NOT SPECIFIED		0.25 Milligram		
FUROSEMIDE	Drug used to treat AE	NOT SPECIFIED		40.0 Milligram		
L-THYROXINE	Suspect	NOT SPECIFIED	Oral	0.5 Milligram		
NOZINAN	Concomitant	NOT SPECIFIED	Oral	1.0 Gram		
PERPHENAZINE	Concomitant	NOT SPECIFIED	Oral	24.0 Milligram		1.0 Month(s)

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Left ventricular failure	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000021303	0	1979-06-15	1979-06-15	Hospital		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
69 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
L-THYROXINE	Suspect	NOT SPECIFIED	Oral	0.2 Milligram	1 every 1 Day(s)	32.0 Day(s)

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.17.0	
Decreased appetite	v.17.0	
Dehydration	v.17.0	
Hypokalaemia	v.17.0	
Muscle spasms	v.17.0	
Somnolence	v.17.0	
Vomiting	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000024806	0	1980-07-23	1980-07-23			Spontaneous	Physician

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	152 Centimetres	54 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
CONTRACEPTIVES	Concomitant	NOT SPECIFIED				
L-THYROXINE	Suspect	NOT SPECIFIED	Oral	0.07 Milligram		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Breath odour	v.17.0	
Dysgeusia	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000024807	0	1980-07-23	1980-07-23			Spontaneous	Physician

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
51 Years	Female	157 Centimetres	59 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
L-THYROXINE	Suspect	TABLET	Oral	0.15 Milligram	1 every 1 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Breath odour	v.17.0	
Dysgeusia	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000037692	0	1983-05-10	1983-05-10	Hospital		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
76 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
AMPICILLIN	Suspect	NOT SPECIFIED	Oral	250.0 Milligram	4 every 1 Day(s)	4.0 Day(s)
CLOXACILLIN	Concomitant	NOT SPECIFIED	Oral	250.0 Milligram	4 every 1 Day(s)	3.0 Day(s)
COLACE	Suspect	NOT SPECIFIED	Oral	2.0 Dosage forms	2 every 1 Day(s)	
DIGOXIN	Suspect	NOT SPECIFIED	Oral	0.12 Milligram	1 every 1 Day(s)	
ELTROXIN	Suspect	TABLET	Oral	100.0 Milligram	1 every 1 Day(s)	
FUROSEMIDE	Suspect	NOT SPECIFIED	Oral	40.0 Milligram	2 every 1 Day(s)	6.0 Day(s)
NITROGLYCERIN PASTE	Suspect	NOT SPECIFIED	Topical		1 every 1 Day(s)	
TALWIN	Concomitant	TABLET	Oral	25.0 Milligram	As required	
TYLENOL WITH CODEINE NO. 3 - TAB	Concomitant	TABLET	Oral	1.0 Dosage forms	As required	1.0 Day(s)

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Rash	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2014-07-13 - 09:53:00 AM
Initial Received Date:	1965-01-01 to 2014-03-31
Latest Received Date:	N/A
Total Number of Reports:	562 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
000039062	0	1983-12-01	1983-12-01	Hospital		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
54 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
DESIPRAMINE	Suspect	TABLET		100.0 Milligram		
FELDENE	Suspect	NOT SPECIFIED	Oral	20.0 Milligram	1 every 1 Day(s)	
FLURAZEPAM HYDROCHLORIDE	Suspect	CAPSULE	Oral	30.0 Milligram		
L-THYROXINE	Suspect	NOT SPECIFIED		0.05 Milligram	1 every 1 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Rash	v.17.0	
Tremor	v.17.0	
Vision blurred	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000041390	0	1984-03-30	1984-03-30	Hospital		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
72 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
DIGOXIN	Concomitant	NOT SPECIFIED	Oral	0.25 Milligram		
DYAZIDE TAB	Concomitant	TABLET	Oral	1.0 Dosage forms		
L-THYROXINE	Suspect	NOT SPECIFIED	Oral	0.15 Milligram		4.0 Year(s)
LASIX	Concomitant	NOT SPECIFIED	Oral	80.0 Milligram		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Thyroid disorder	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000042323	0	1984-01-23	1984-01-23			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			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
SYNTHROID	Suspect	TABLET	Oral	0.1 Milligram		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Diarrhoea	v.17.0	
Gastritis	v.17.0	
Nausea	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000043019	0	1984-07-23	1984-07-23	Other		Spontaneous	Physician

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
44 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
SYNTHROID	Suspect	NOT SPECIFIED	Oral	0.1 Milligram		15.0 Month(s)
VALIUM NOS	Concomitant	NOT SPECIFIED		5.0 Milligram		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Paraesthesia	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000044283	0	1984-08-08	1984-08-08			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

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
SYNTHROID	Suspect	NOT SPECIFIED	Oral	1.5 Milligram		4.0 Month(s)

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hyperhidrosis	v.17.0	
Insomnia	v.17.0	
Irritability	v.17.0	
Myocardial infarction	v.17.0	
Nervousness	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000049385	0	1985-10-03	1985-10-03	Hospital		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
58 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
BEROTEC	Concomitant	NOT SPECIFIED	Inhalation	8.0 Dosage forms		
ELTROXIN	Suspect	TABLET	Oral	0.2 Milligram		20.0 Year(s)
HYDROCHLOROTHIAZIDE	Concomitant	TABLET	Oral	50.0 Milligram		
TAGAMET	Concomitant	NOT SPECIFIED	Oral	300.0 Milligram		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Drug level increased	v.17.0	
Drug level increased	v.17.0	
Hypertension	v.17.0	
Tachycardia	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000052443	0	1986-01-06	1986-01-06	Hospital		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
				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
BIQUIN DURULES 250 MG	Suspect	TABLET (EXTENDED-RELEASE)	Oral			
DIGOXIN	Suspect	NOT SPECIFIED				
DYAZIDE TAB	Suspect	TABLET				
ELTROXIN	Suspect	TABLET	Oral			
HEPARIN SODIUM INJECTION, USP	Suspect	SOLUTION INTRAVENOUS				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Ecchymosis	v.17.0	
Haematuria	v.17.0	
Haemoptysis	v.17.0	
Thrombocytopenia	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000056650	0	1986-09-29	1986-09-29	Hospital		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
69 Years	Male		50 Kilograms	Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration
SYNTHROID	Suspect	NOT SPECIFIED	Oral	0.1 Milligram	1 every 1 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dermatitis	v.17.0	
Pruritus	v.17.0	
Rash	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000061608	0	1987-09-25	1987-09-25	Other		Spontaneous	Physician

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
68 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
ELTROXIN	Suspect	TABLET	Oral		1 every 1 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Eye pain	v.17.0	
Lacrimation increased	v.17.0	
Periorbital oedema	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000064357	0	1987-06-17	1987-06-17	Hospital		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
76 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
ATROVENT	Concomitant	NOT SPECIFIED	Inhalation			
BECLOVENT - AEM 50MCG/AEM	Concomitant	METERED-DOSE (AEROSOL)	Inhalation			
LEVOTHYROXINE	Suspect	NOT SPECIFIED	Oral	200.0 Milligram		
VENTOLIN FOR INHALATION	Concomitant	NOT SPECIFIED				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactoid reaction	v.17.0	
Dyspnoea	v.17.0	
Fatigue	v.17.0	
Hot flush	v.17.0	
Weight decreased	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000065643	0	1988-06-06	1988-06-06	Hospital		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
				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
EXCIPIENTS	Suspect	NOT SPECIFIED				
THYROXINE	Suspect	NOT SPECIFIED				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypersensitivity	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000066233	0	1988-09-02	1988-09-02	Hospital		Spontaneous	

Serious report?	Death:		Disability:		Congenital Anomaly:	
Yes	Life Threatening:		Hospitalization:		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
INSULIN	Concomitant	NOT SPECIFIED				
SYNTHROID	Suspect	NOT SPECIFIED	Oral	0.1 Milligram	1 every 1 Day(s)	5.0 Day(s)

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.17.0	
Chest discomfort	v.17.0	
Dizziness	v.17.0	
Dyspnoea	v.17.0	
Lethargy	v.17.0	
Palpitations	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000069363	0	1989-08-02	1989-08-02	Hospital		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
38 Years	Female	168 Centimetres	60 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
ELTROXIN	Suspect	TABLET	Oral	0.15 Milligram	2 every 1 Week(s)	
STEROID(S)	Drug used to treat AE	NOT SPECIFIED				
SYNTHROID	Suspect	NOT SPECIFIED	Oral	0.2 Milligram	3 every 1 Week(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Erythema multiforme	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000071308	0	1989-05-01	1989-05-01	MAH		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
64 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
ALLBEE WITH C 550 CAP	Concomitant	CAPSULE				
CYTOMEL	Suspect	NOT SPECIFIED		0.25 Milligram	1 every 1 Day(s)	
ELTROXIN	Suspect	TABLET	Oral			
KELP	Concomitant	TABLET				
SYNTHROID	Suspect	NOT SPECIFIED	Oral			
TYLENOL WITH CODEINE NO. 3 - TAB	Concomitant	TABLET				
VITAMIN A	Concomitant	NOT SPECIFIED				
VITAMIN D	Concomitant	NOT SPECIFIED				
VITAMIN E	Concomitant	NOT SPECIFIED				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.17.0	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Muscle spasms	v.17.0	
Muscle spasticity	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000073312	0	1990-06-28	1990-06-28			Spontaneous	Physician

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
35 Years	Female	160 Centimetres	52 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
ELTROXIN	Suspect	TABLET	Oral	100.0 Microgram		
ELTROXIN	Suspect	TABLET	Oral	150.0 Microgram		
SYNTHROID	Concomitant	NOT SPECIFIED	Oral	0.12 Milligram		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Therapeutic response decreased	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000075467	0	1990-12-10	1990-12-10	Hospital		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
66 Years	Female	168 Centimetres	64 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
ALPRAZOLAM	Concomitant	TABLET	Oral			
BENADRYL	Drug used to treat AE	NOT SPECIFIED		25.0 Milligram	3 every 1 Day(s)	
ELTROXIN	Suspect	TABLET	Oral	0.05 Milligram	1 every 1 Day(s)	6.0 Day(s)

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pruritus	v.17.0	
Rash maculo-papular	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000076180	0	1991-02-19	1991-02-19	Hospital		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
78 Years	Female	164 Centimetres	56 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
COUMADIN	Suspect	NOT SPECIFIED	Oral			
ELTROXIN	Suspect	TABLET	Oral	0.1 Milligram		
MEVACOR	Concomitant	TABLET	Oral	20.0 Milligram		
OS-CAL	Concomitant	TABLET	Oral	500.0 Milligram		
TYLENOL WITH CODEINE NO. 3 - TAB	Concomitant	TABLET	Oral		As required	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Drug interaction	v.17.0	
Prothrombin level increased	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2014-07-13 - 09:53:00 AM
Initial Received Date:	1965-01-01 to 2014-03-31
Latest Received Date:	N/A
Total Number of Reports:	562 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
000076743	0	1991-04-16	1991-04-16	Hospital		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
89 Years	Female	150 Centimetres	45 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
ELTROXIN	Suspect	TABLET	Oral	100.0 Microgram		
TYLENOL	Concomitant	NOT SPECIFIED	Oral	650.0 Milligram	As required	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Therapeutic response decreased	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000078020	0	1991-06-03	1991-06-03			Spontaneous	Physician

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
				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
NITRONG SR SRT 2.6MG	Concomitant	TABLET (EXTENDED-RELEASE)	Oral	20.0 Milligram	3 every 1 Day(s)	
SYNTHROID	Suspect	NOT SPECIFIED	Oral	0.05 Milligram	1 every 1 Day(s)	2.0 Day(s)
XANAX	Concomitant	NOT SPECIFIED		0.5 Milligram	As required	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Somnolence	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000080614	0	1991-10-09	1991-10-09	MAH		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
46 Years	Female		50 Kilograms	Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration
ELTROXIN	Suspect	TABLET	Oral	100.0 Milligram	1 every 1 Day(s)	6.0 Day(s)
ESTRADERM	Concomitant	DISC (EXTENDED-RELEASE)	Topical			
LOSEC	Concomitant	NOT SPECIFIED	Oral	20.0 Milligram	1 every 1 Day(s)	
PROZAC	Concomitant	NOT SPECIFIED	Oral	20.0 Milligram	1 every 1 Day(s)	
SULCRATE	Concomitant	NOT SPECIFIED	Oral			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Generalised oedema	v.17.0	
Pruritus	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000080622	0	1991-10-09	1991-10-09	MAH		Spontaneous	

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			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
ELTROXIN	Suspect	TABLET	Oral	50.0 Microgram	3 every 1 Day(s)	2.0 Day(s)

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Urticaria	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000080727	0	1992-07-21	1992-07-21	Hospital		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
74 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
DIGOXIN	Suspect	NOT SPECIFIED	Oral	0.25 Milligram		
DILTIAZEM	Concomitant	TABLET (EXTENDED-RELEASE)	Oral	90.0 Milligram	2 every 1 Day(s)	
ELTROXIN	Suspect	TABLET	Oral	150.0 Microgram		
LASIX	Concomitant	NOT SPECIFIED	Oral	20.0 Milligram	1 every 1 Day(s)	
LIDOCAINE	Drug used to treat AE	NOT SPECIFIED				
SLOW K 600MG	Concomitant	TABLET (EXTENDED-RELEASE)	Oral	1.0 Dosage forms	1 every 1 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Atrial fibrillation	v.17.0	
Drug interaction	v.17.0	
Drug level increased	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000082483	0	1993-01-20	1993-01-20	MAH		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
30 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
BENZTROPINE MESYLATE	Concomitant	NOT SPECIFIED	Oral			
CHLORPROMAZINE	Concomitant	NOT SPECIFIED	Oral			
ELTROXIN	Suspect	TABLET	Oral	0.05 Milligram		
EPIVAL	Concomitant	NOT SPECIFIED	Oral			
LITHIUM CARBONATE	Concomitant	NOT SPECIFIED	Oral	1200.0 Milligram	1 every 1 Day(s)	
ZOLOFT	Concomitant	CAPSULE	Oral			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000083089	0	1991-07-03	1991-07-03			Spontaneous	Physician

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
28 Years	Male	172 Centimetres	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
ELTROXIN	Suspect	TABLET	Oral	100.0 Microgram		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pruritus	v.17.0	
Rash maculo-papular	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000087025	0	1995-01-10	1995-01-10	MAH		Spontaneous	

Serious report?	Death:		Disability:		Congenital Anomaly:	
No	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
ELTROXIN	Suspect	TABLET	Oral			
IMITREX	Suspect	NOT SPECIFIED	Oral	100.0 Milligram	As required	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Drug interaction	v.17.0	
Weight increased	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000087026	0	1995-01-10	1995-01-10	MAH		Spontaneous	

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	152 Centimetres	112 Kilograms	Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration
ANTIHISTAMINIC DRUGS	Drug used to treat AE	NOT SPECIFIED				
ELTROXIN	Suspect	TABLET	Oral			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Rash	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000087153	0	1995-01-10	1995-01-10	MAH		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
42 Years	Female		64 Kilograms	Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration
BENADRYL	Concomitant	NOT SPECIFIED				
ELTROXIN	Suspect	TABLET	Oral			
SELDANE	Concomitant	NOT SPECIFIED				
VITAMIN B COMPLEX	Concomitant	NOT SPECIFIED				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.17.0	
Dizziness	v.17.0	
Nausea	v.17.0	
Pain	v.17.0	
Palpitations	v.17.0	
Skin discolouration	v.17.0	
Tremor	v.17.0	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Urinary retention	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000087740	0	1995-08-09	1995-08-09	MAH		Spontaneous	

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
BIAXIN	Concomitant	NOT SPECIFIED	Oral			
IRON	Concomitant	NOT SPECIFIED				
SYNTHROID	Suspect	TABLET	Oral	0.17 Milligram	1 every 1 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Therapeutic response increased	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2014-07-13 - 09:53:00 AM
Initial Received Date:	1965-01-01 to 2014-03-31
Latest Received Date:	N/A
Total Number of Reports:	562 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
000088986	0	1995-09-29	1995-09-29	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
50 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
ELTROXIN	Suspect	TABLET	Oral			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Gastrointestinal haemorrhage	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000097665	0	1968-07-18	1968-07-18	Hospital		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
65 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
ELTROXIN	Suspect	TABLET	Oral	0.05 Milligram		2.0 Day(s)
PENBRITIN	Suspect	NOT SPECIFIED		1000.0 Milligram		1.0 Day(s)
PHISOHEX	Suspect	EMULSION				3.0 Day(s)

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Rash maculo-papular	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000097672	0	1968-08-14	1968-08-14	Hospital		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
80 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
AMPICILLIN	Suspect	NOT SPECIFIED		2.0 Gram		1.0 Week(s)
ELTROXIN	Suspect	TABLET	Oral	1.0 Teaspoonful		1.0 Week(s)

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Petechiae	v.17.0	
Thrombocytopenic purpura	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000098102	0	1968-10-01	1968-10-01			Spontaneous	Physician

Serious report?	Death:	Disability:	Congenital Anomaly:
No	Life Threatening:	Hospitalization:	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
No duplicate or linked report.	

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration
SYNTHROID	Suspect	NOT SPECIFIED	Oral	0.4 Milligram		1.0 Day(s)

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Urticaria	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000099441	0	1968-07-18	1968-07-18	Hospital		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
42 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
ELTROXIN	Suspect	TABLET	Oral	0.05 Milligram		12.0 Day(s)
HYGROTON 50MG	Suspect	TABLET	Oral	100.0 Milligram		12.0 Day(s)
TENUATE DOSPAN	Suspect	TABLET (EXTENDED-RELEASE)	Oral	25.0 Milligram		12.0 Day(s)

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Rash maculo-papular	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000101247	0	1970-01-01	1970-01-01	Hospital		Spontaneous	

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
CYTOMEL	Suspect	NOT SPECIFIED		37.0 Microgram		14.0 Day(s)
L-THYROXINE	Suspect	NOT SPECIFIED	Oral	0.2 Milligram		12.0 Month(s)
VALIUM ORAL	Suspect	NOT SPECIFIED		3.0 Milligram		19.0 Day(s)

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Headache	v.17.0	
Pruritus	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000104070	0	1970-04-28	1970-04-28			Spontaneous	Physician

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
55 Years	Female	170 Centimetres	60 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
SYNTHROID	Suspect	NOT SPECIFIED	Oral			5.0 Month(s)

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.17.0	
Paraesthesia	v.17.0	
Pruritus	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000104083	0	1970-05-26	1970-05-26			Spontaneous	Physician

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
72 Years	Female	152 Centimetres	52 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
SYNTHROID	Suspect	NOT SPECIFIED	Oral	0.2 Milligram		5.0 Month(s)

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Malaise	v.17.0	
Myalgia	v.17.0	
Pyrexia	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000104815	0	1970-11-10	1970-11-10	Hospital		Study	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
49 Years	Female	170 Centimetres	81 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
ELTROXIN	Suspect	TABLET	Oral	0.3 Milligram		80.0 Week(s)
FESOFOR	Concomitant	NOT SPECIFIED	Oral	15.0 Grain		79.0 Day(s)
INSULIN PROTAMINE ZINC	Suspect	NOT SPECIFIED	Subcutaneous	60.0 Units		17.0 Day(s)
MELLARIL	Suspect	NOT SPECIFIED	Oral	300.0 Milligram		11.0 Day(s)

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypoglycaemia	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2014-07-13 - 09:53:00 AM
Initial Received Date:	1965-01-01 to 2014-03-31
Latest Received Date:	N/A
Total Number of Reports:	562 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
000106037	0	1970-10-16	1970-10-16	Hospital		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
75 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
CHEESE	Concomitant	TABLET	Oral	1.0 Dosage forms		
DARVON N 100MG CAP	Concomitant	CAPSULE	Oral			
DARVON N COMPOUND PULVULE 405	Concomitant	CAPSULE	Oral		6 every 1 Day(s)	
DIGOXIN	Concomitant	NOT SPECIFIED	Oral	0.25 Milligram		
MODANE	Concomitant	NOT SPECIFIED	Oral	1.0 Dosage forms		
NOLUDAR	Concomitant	NOT SPECIFIED	Oral	300.0 Milligram		
SYNTHROID	Suspect	NOT SPECIFIED	Oral	0.05 Milligram		
VALIUM ORAL	Concomitant	NOT SPECIFIED	Oral	2.5 Milligram	3 every 1 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.17.0	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Nausea	v.17.0	
Vomiting	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000107649	0	1971-05-17	1971-05-17			Spontaneous	Physician

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
51 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
HYDRODIURIL	Concomitant	TABLET	Oral		Cyclical	
PREMARIN	Concomitant	NOT SPECIFIED	Oral			
SYNTHROID	Suspect	NOT SPECIFIED	Oral	0.15 Milligram		50.0 Day(s)

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dermatitis	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000109981	0	1971-10-19	1971-10-19	Hospital		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
61 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
DEMEROL	Concomitant	NOT SPECIFIED	Intramuscular	50.0 Milligram	4 every 1 Day(s)	
SYNTHROID	Suspect	NOT SPECIFIED	Oral	0.1 Milligram		
TUINAL	Concomitant	NOT SPECIFIED	Oral	100.0 Milligram		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Rash	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000112650	0	1972-09-25	1972-09-25			Spontaneous	Pharmacist

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
35 Years	Male	180 Centimetres	77 Kilograms	Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration
ELTROXIN	Suspect	TABLET	Oral	0.1 Milligram		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypothyroidism	v.17.0	
Weight increased	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000113742	0	1972-11-24	1972-11-24	Hospital		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
82 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
DIGOXIN	Suspect	NOT SPECIFIED	Oral	0.25 Milligram		
DYAZIDE TAB	Concomitant	TABLET	Oral			
PENICILLIN NOS	Concomitant	NOT SPECIFIED				
PRONESTYL	Concomitant	NOT SPECIFIED				
SYNTHROID	Suspect	NOT SPECIFIED	Oral	0.4 Milligram		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Drug interaction	v.17.0	
Drug level increased	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000115789	0	1997-03-05	1997-03-05	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
66 Years	Female	168 Centimetres	57 Kilograms	Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration
ELTROXIN	Suspect	TABLET	Oral	100.0 Milligram	every 1 Day(s)	
SERZONE-5HT2	Suspect	TABLET	Oral	150.0 Milligram	every 1 Day(s)	4.0 Week(s)

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Atrial fibrillation	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000115944	0	1997-01-07	1997-01-07	Community	SYN00297	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
70 Years	Female		61 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
ETRAFON	Concomitant	TABLET	Oral		1 every 1 Day(s)	
FLURAZEPAM HYDROCHLORIDE	Concomitant	CAPSULE	Oral	30.0 Milligram	1 every 1 Day(s)	
LOVASTATIN	Concomitant	TABLET	Oral			
PREMARIN	Concomitant	TABLET	Oral	0.625 Milligram	1 every 1 Day(s)	
SYNTHROID	Suspect	TABLET	Oral	0.05 Milligram	1 every 1 Day(s)	3.5 Month(s)

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Infection	v.17.0	
Rash papular	v.17.0	
Skin infection	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000116295	0	1997-11-25	1998-01-13	MAH	62363	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
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
ANAESTHESIA GENERAL	Suspect	NOT SPECIFIED				
LEVOTHYROXINE	Suspect	TABLET	Oral			
LORAZEPAM	Suspect	TABLET	Oral			
PAXIL	Suspect	TABLET	Oral			
RISPERDAL	Suspect	NOT SPECIFIED	Oral			
RISPERDAL	Suspect	NOT SPECIFIED	Intra-uterine			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Oligohydramnios	v.17.0	
Premature baby	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2014-07-13 - 09:53:00 AM
Initial Received Date:	1965-01-01 to 2014-03-31
Latest Received Date:	N/A
Total Number of Reports:	562 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
000116604	0	1998-02-25	1998-02-25	MAH	000062	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
82 Years	Female	157 Centimetres	64 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
CAPTOPRIL	Concomitant	NOT SPECIFIED		75.0 Milligram	every 1 Day(s)	
IRON	Concomitant	NOT SPECIFIED		600.0 Milligram	every 1 Day(s)	
NITROFURANTOIN	Concomitant	NOT SPECIFIED	Oral	100.0 Milligram	every 1 Day(s)	
POTASSIUM (NOS)	Concomitant	NOT SPECIFIED		3600.0 Milligram	every 1 Day(s)	
RANITIDINE	Concomitant	NOT SPECIFIED	Oral	300.0 Milligram	every 1 Day(s)	
SYNTHROID	Suspect	TABLET	Oral		every 1 Day(s)	
VITAMIN B12	Concomitant	NOT SPECIFIED		100.0 Milligram		
WARFARIN	Concomitant	NOT SPECIFIED	Oral	2.0 Milligram		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain upper	v.17.0	
Dermatitis	v.17.0	
Diarrhoea	v.17.0	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Palpitations	v.17.0	
Pyrexia	v.17.0	
Tongue oedema	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000117610	0	1998-04-30	1998-04-30	Community		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
71 Years	Female	157 Centimetres	86 Kilograms	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
ASA	Drug used to treat AE	NOT SPECIFIED				
BETOPTIC S OPH SUS 0.25%	Concomitant	SUSPENSION OPHTHALMIC	Ophthalmic	0.25 Percent	2 every 1 Day(s)	
ELTROXIN	Suspect	TABLET	Oral	200.0 Microgram	every 1 Day(s)	
HEPARIN SODIUM INJECTION, USP	Drug used to treat AE	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)			
HYDROCHLOROTHIAZIDE	Concomitant	TABLET	Oral	50.0 Milligram	every 1 Day(s)	
MORPHINE	Drug used to treat AE	NOT SPECIFIED				
NITROGLYCERIN INJECTION USP	Drug used to treat AE	SOLUTION INTRAVENOUS	Intravenous (not otherwise specified)			
PERIACTIN TAB 4MG	Concomitant	TABLET	Parenteral	4.0 Milligram	2 every 1 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood creatine phosphokinase increased	v.17.0	
Chest discomfort	v.17.0	
Chest pain	v.17.0	
Drug level increased	v.17.0	
Dyspnoea	v.17.0	
Hyperhidrosis	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000118759	0	1998-07-20	1998-07-20	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
				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
L-THYROXINE	Suspect	NOT SPECIFIED	Unknown	0.1 Milligram	1 every 1 Day(s)	18.0 Year(s)

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.17.0	
Confusional state	v.17.0	
Dizziness	v.17.0	
Gastrointestinal disorder	v.17.0	
Malaise	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2014-07-13 - 09:53:00 AM
Initial Received Date:	1965-01-01 to 2014-03-31
Latest Received Date:	N/A
Total Number of Reports:	562 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
000119137	0	1998-08-19	1998-10-26	MAH	000131	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
60 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
COUMADIN	Concomitant	NOT SPECIFIED	Unknown			17.0 Month(s)
LORAZEPAM	Concomitant	NOT SPECIFIED	Oral			
METRONIDAZOLE	Concomitant	NOT SPECIFIED	Oral	150.0 Milligram	every 1 Day(s)	
SYNTHROID	Suspect	NOT SPECIFIED	Oral	0.125 Microgram	every 1 Day(s)	14.0 Day(s)
VITAMIN B12	Concomitant	INJECTION			1 every 1 Week(s)	
WARFARIN	Concomitant	NOT SPECIFIED	Oral			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain	v.17.0	
Atrial fibrillation	v.17.0	
Diarrhoea	v.17.0	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Nausea	v.17.0	
Vomiting	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000119216	0	1998-08-27	1998-08-27	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
83 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
ACETYLSALICYLIC ACID ENT CTD	Concomitant	TABLET (ENTERIC-COATED)		325.0 Milligram		
CENTRUM TABLETS	Concomitant	TABLET				
ELTROXIN	Suspect	TABLET		100.0 Microgram		
LORAZEPAM	Concomitant	NOT SPECIFIED		0.5 Milligram		
OS-CAL	Concomitant	TABLET		500.0 Milligram		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pruritus	v.17.0	
Urticaria	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000119558	0	1998-09-28	1998-09-28	MAH	98412	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
58 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
COLESTIPOL	Suspect	TABLET	Oral	4.0 Dosage forms	every 1 Day(s)	
ESTRADIOL	Concomitant	NOT SPECIFIED				
FERROUS GLYCINE SULFATE	Concomitant	NOT SPECIFIED				
PREDNISONE	Drug used to treat AE	NOT SPECIFIED				
SPIRONOLACTONE	Drug used to treat AE	TABLET				
THYROXINE	Suspect	NOT SPECIFIED		0.15 Milligram	every 1 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain	v.17.0	
Alanine aminotransferase increased	v.17.0	
Aspartate aminotransferase increased	v.17.0	
Blood alkaline phosphatase increased	v.17.0	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood bilirubin increased	v.17.0	
Hyperthyroidism	v.17.0	
Jaundice	v.17.0	
Liver function test abnormal	v.17.0	
Liver injury	v.17.0	
Nausea	v.17.0	
Pruritus	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000120254	0	1998-11-25	1998-11-25	MAH	USA005434	Published	Pharmacist

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
67 Years	Female			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
DIMENHYDRINATE	Concomitant	NOT SPECIFIED				
IPRATROPIUM	Concomitant	NOT SPECIFIED	Oral	40.0 Microgram	4 every 1 Day(s)	
LEVOTHYROXINE	Suspect	NOT SPECIFIED	Oral	150.0 Microgram	every 1 Day(s)	
MORPHINE	Concomitant	NOT SPECIFIED				
PHENYTOIN	Suspect	NOT SPECIFIED	Oral	250.0 Milligram	every 1 Day(s)	
SALBUTAMOL	Concomitant	INHALATION	Oral	200.0 Microgram	4 every 1 Day(s)	
TYLENOL W CODEINE NO3 TAB	Concomitant	TABLET				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.17.0	
Blood alkaline phosphatase increased	v.17.0	
Fall	v.17.0	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Gait disturbance	v.17.0	
Muscular weakness	v.17.0	
Pathological fracture	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000121384	0	1999-02-05	1999-02-05	MAH	000255	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			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
SYNTHROID	Suspect	TABLET	Oral	200.0 Microgram	every 1 Day(s)	4.0 Month(s)

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Depressed level of consciousness	v.17.0	
Fall	v.17.0	
Fatigue	v.17.0	
Listless	v.17.0	
Mental impairment	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000121430	0	1999-02-09	1999-02-09	MAH	000254	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
SYNTHROID	Suspect	TABLET	Oral			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Atrial fibrillation	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000121701	0	1998-01-19	1998-01-19	MAH	CAN000051	Spontaneous	Physician

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
73 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
LIPITOR	Concomitant	TABLET	Oral	20.0 Milligram	every 1 Day(s)	
SERC	Concomitant	TABLET	Oral	4.0		
SYNTHROID	Suspect	TABLET	Oral	50.0 Microgram	2 every 1 Day(s)	16.0 Year(s)

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.17.0	
Hot flush	v.17.0	
Nausea	v.17.0	
Vertigo	v.17.0	
Vision blurred	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000122347	0	1999-03-18	1999-03-26	MAH	993948	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
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
DIPHENHYDRAMINE HYDROCHLORIDE INJECTION USP	Drug used to treat AE	LIQUID INTRAMUSCULAR				
ELTROXIN	Suspect	TABLET	Oral	100.0 Microgram	1 every 1 Day(s)	
EPIPEN	Drug used to treat AE	SOLUTION INTRAMUSCULAR				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.17.0	4 Day(s)

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000122884	0	1999-04-13	1999-04-13	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
83 Years	Female		45 Kilograms	Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration
CIPROFLOXACIN	Concomitant	NOT SPECIFIED	Oral	500.0 Milligram	2 every 1 Day(s)	1.0 Week(s)
LEVOTHYROXINE	Suspect	NOT SPECIFIED	Oral	100.0 Microgram	every 1 Day(s)	30.0 Year(s)
METOPROLOL	Concomitant	NOT SPECIFIED	Oral	50.0 Milligram	2 every 1 Day(s)	3.0 Month(s)
METRONIDAZOLE	Concomitant	NOT SPECIFIED	Oral	500.0 Milligram	3 every 1 Day(s)	1.0 Week(s)
PHENOBARBITAL	Concomitant	NOT SPECIFIED	Oral	30.0 Milligram	2 every 1 Day(s)	40.0 Year(s)
PROPAFENONE	Drug used to treat AE	NOT SPECIFIED	Oral	150.0 Milligram	2 every 1 Day(s)	
RAMIPRIL	Concomitant	NOT SPECIFIED	Oral	5.0 Milligram	1 every 1 Day(s)	3.0 Month(s)

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Atrial fibrillation	v.17.0	
Convulsion	v.17.0	
Hyperthyroidism	v.17.0	
Palpitations	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000123422	0	1999-05-10	1999-05-10	MAH	000430	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
ESTRADIOL	Concomitant	NOT SPECIFIED	Transdermal	3.0	every 1 Day(s)	
HYDROCHLOROTHIAZIDE	Concomitant	TABLET	Oral	25.0 Milligram	every 1 Day(s)	
PLAVIX	Concomitant	TABLET	Oral			
PRAVASTATIN SODIUM	Concomitant	TABLET	Oral	20.0	every 1 Day(s)	
SYNTHROID	Suspect	NOT SPECIFIED	Oral	125.0 Microgram	every 1 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cerebrovascular accident	v.17.0	
Medication error	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000124275	0	1997-11-20	1997-11-20	MAH	JACAN16524	Spontaneous	Other 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
	Male		2 Kilograms	Death

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	000124478

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration
ADVIL	Suspect	TABLET	Transplacental			
ANALGESICS	Suspect	NOT SPECIFIED	Transplacental			
ELTROXIN	Suspect	TABLET	Transplacental	0.05 Milligram	every 1 Day(s)	
MATERNA	Suspect	TABLET	Transplacental	1.0 Dosage forms	every 1 Day(s)	6.0 Month(s)
PREPULSID	Suspect	TABLET	Transplacental	1.0 Dosage forms	4 every 1 Day(s)	5.0 Day(s)

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Infection	v.17.0	
Premature baby	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000124478	0	1997-11-20	1997-11-20	MAH	62139	Spontaneous	Other 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
29 Years	Female			Recovered/resolved

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	000124275

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration
ADVIL	Concomitant	TABLET	Oral			
ADVIL	Suspect	TABLET	Oral			
ANALGESICS	Suspect	NOT SPECIFIED	Oral			
ELTROXIN	Suspect	TABLET	Oral	0.05 Milligram	every 1 Day(s)	
MATERNA	Suspect	TABLET	Oral	1.0 Dosage forms	1 every 1 Day(s)	6.0 Month(s)
PREPULSID	Suspect	TABLET	Oral	1.0 Dosage forms	4 every 1 Day(s)	5.0 Day(s)

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Premature labour	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2014-07-13 - 09:53:00 AM
Initial Received Date:	1965-01-01 to 2014-03-31
Latest Received Date:	N/A
Total Number of Reports:	562 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
000124523	0	1999-06-04	1999-06-04	MAH	53877	Safety Update Report	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
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
ASTEMIZOLE TAB 10MG	Suspect	TABLET	Oral	10.0 Milligram	1 every 1 Day(s)	4.0 Month(s)
LEVOTHYROXINE	Suspect	NOT SPECIFIED	Unknown			
MARIJUANA	Concomitant	NOT SPECIFIED				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abortion	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000124672	0	1999-06-25	1999-06-25	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
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
ELTROXIN	Suspect	TABLET	Unknown			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dysphagia	v.17.0	
Dyspnoea	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000125180	0	1999-07-21	1999-07-21	MAH	991121	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
87 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
AMIODARONE	Drug used to treat AE	NOT SPECIFIED	Unknown	100.0 Milligram	every 1 Day(s)	
CELEXA	Suspect	TABLET	Oral	10.0 Milligram	every 1 Day(s)	
LEVOTHYROXINE	Suspect	TABLET	Oral	0.3 Milligram	every 1 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Atrial fibrillation	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000125244	0	1997-10-07	1997-10-07	Hospital		Spontaneous	

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
81 Years	Female	160 Centimetres	73 Kilograms	Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration
ELTROXIN	Suspect	TABLET	Oral	50.0 Microgram	every 1 Day(s)	
ENTROPHEN	Concomitant	TABLET (DELAYED-RELEASE)	Oral	325.0 Milligram	every 1 Day(s)	
PLENDIL	Suspect	TABLET (EXTENDED-RELEASE)	Oral	5.0 Milligram	every 1 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Ear pain	v.17.0	
Flushing	v.17.0	
Headache	v.17.0	
Tachycardia	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000125703	0	1999-08-09	1999-08-09	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
43 Years	Female	163 Centimetres	57 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
ELTROXIN	Suspect	TABLET	Oral	50.0 Microgram	every 1 Day(s)	3.0 Week(s)

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Rash maculo-papular	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000127256	0	1999-11-09	1999-11-09	Other		Spontaneous	Pharmacist

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
41 Years	Female	150 Centimetres	64 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
LEVOTEC	Suspect	TABLET	Oral	175.0 Microgram	every 1 Day(s)	1.0 Day(s)

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Tremor	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000127459	0	1999-11-15	1999-11-15	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
80 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
ATIVAN	Drug used to treat AE	NOT SPECIFIED	Unknown			
CELEBREX	Suspect	CAPSULE	Unknown			
CYPROHEPTADINE HYDROCHLORIDE TABLET USP	Drug used to treat AE	TABLET		4.0 Milligram	6 every 1 Day(s)	
ELTROXIN	Suspect	TABLET	Unknown			
FLUIDS	Drug used to treat AE	NOT SPECIFIED	Unknown			
PARNATE	Suspect	TABLET	Unknown			30.0 Year(s)
ZYPREXA	Suspect	TABLET	Unknown			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Confusional state	v.17.0	
Depressed level of consciousness	v.17.0	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Muscle rigidity	v.17.0	
Pyrexia	v.17.0	
Serotonin syndrome	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000127859	0	1999-11-26	1999-11-26	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
65 Years	Female	163 Centimetres	89 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
CELEBREX	Suspect	CAPSULE	Oral	100.0 Milligram	2 every 1 Day(s)	1.0 Month(s)
CIPRO	Concomitant	NOT SPECIFIED	Oral	500.0 Milligram	2 every 1 Day(s)	2.0 Day(s)
GLUCOSAMINE	Concomitant	TABLET	Oral	500.0 mL	2 every 1 Day(s)	
LEVOTHYROXINE	Suspect	NOT SPECIFIED	Oral	0.125 Milligram	1 every 1 Day(s)	
LORAZEPAM	Concomitant	NOT SPECIFIED	Unknown	1.0 Milligram	2 every 1 Day(s)	
TYLENOL	Concomitant	NOT SPECIFIED	Unknown	500.0 Milligram	As required	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Haemorrhage	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000128459	0	2000-01-05	2000-01-05	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
76 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
C.E.S. TABLETS	Suspect	TABLET				
NOVO-FAMOTIDINE	Suspect	TABLET				
THYROXINE	Suspect	NOT SPECIFIED				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain	v.17.0	
Vomiting	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000129012	0	2000-02-07	2000-02-07	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
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
ELTROXIN	Drug used to treat AE	TABLET				
SYNTHROID	Suspect	NOT SPECIFIED	Oral	0.175 Microgram	every 1 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood thyroid stimulating hormone increased	v.17.0	
Drug ineffective	v.17.0	
Fatigue	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000129965	0	2000-03-23	2000-03-23	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
47 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
CIMETIDINE	Concomitant	NOT SPECIFIED	Unknown	600.0 Milligram	2 every 1 Day(s)	
PRINIVIL	Concomitant	TABLET	Unknown	10.0 Milligram	1 every 1 Day(s)	
SYNTHROID	Suspect	NOT SPECIFIED	Unknown	50.0 Microgram	every 1 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Erectile dysfunction	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000130461	0	2000-04-11	2000-04-11	MAH	CA00226	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
27 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
DEPO-PROVERA STERILE AQUEOUS SUSPENSION 150 MG/ML	Suspect	SUSPENSION INTRAMUSCULAR	Intramuscular	150.0 Milligram	4 every 1 Year(s)	
ENOXAPARIN	Concomitant	INJECTION	Unknown			
LEVOTHYROXINE	Suspect	NOT SPECIFIED	Unknown			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Deep vein thrombosis	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000130537	0	2000-04-14	2000-04-26	MAH	CD005011	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
49 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
THYROXINE	Suspect	NOT SPECIFIED	Oral	0.15 Milligram	every 1 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hyperhidrosis	v.17.0	
Palpitations	v.17.0	
Tachycardia	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000131144	0	2000-05-03	2001-07-25	MAH	200113506GDS	Spontaneous	Physician

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
81 Years	Female	177 Centimetres	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
BAYCOL	Suspect	TABLET	Oral	0.3 Milligram	every 1 Day(s)	3.0 Day(s)
LEVOTHYROXINE	Suspect	NOT SPECIFIED	Oral	125.0 Microgram	every 1 Day(s)	3.0 Day(s)
RESUSCITATION MEDS	Drug used to treat AE	NOT SPECIFIED				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic shock	v.17.0	
Asphyxia	v.17.0	
Cardiac arrest	v.17.0	
Cold sweat	v.17.0	
Dyspnoea	v.17.0	
Face oedema	v.17.0	
Hyperhidrosis	v.17.0	
Laryngeal oedema	v.17.0	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Periorbital oedema	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2014-07-13 - 09:53:00 AM
Initial Received Date:	1965-01-01 to 2014-03-31
Latest Received Date:	N/A
Total Number of Reports:	562 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
000132032	0	1996-05-16	1996-05-16	MAH	SYN00396	Spontaneous	Pharmacist

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
80 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
ARTHROTEC	Concomitant	TABLET	Unknown			
RANITIDINE	Drug used to treat AE	NOT SPECIFIED	Unknown			
SYNTHROID	Suspect	NOT SPECIFIED	Oral			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal distension	v.17.0	
Chest pain	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000132034	0	1995-12-07	1996-05-16	MAH	SYN00595	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
RED DYE	Suspect	NOT SPECIFIED				
RED DYE	Suspect	NOT SPECIFIED	Unknown			
SYNTHROID	Suspect	NOT SPECIFIED	Oral	125.0 Microgram	every 1 Day(s)	4.0 Year(s)

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Mood swings	v.17.0	
Nausea	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000132038	0	1997-03-17	1997-03-17	MAH	SYN00597	Spontaneous	Physician

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
SYNTHROID	Suspect	NOT SPECIFIED	Oral	75.0 Microgram	every 1 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain	v.17.0	
Depression	v.17.0	
Diarrhoea	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000132044	0	1997-01-07	1997-01-07	MAH	SYN00197	Spontaneous	Pharmacist

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
80 Years	Female		59 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
ETIDRONATE	Concomitant	TABLET	Unknown	200.0 Milligram		
OXYBUTYNIN	Concomitant	NOT SPECIFIED	Oral	5.0 Milligram	3 every 1 Day(s)	
PREMARIN	Concomitant	NOT SPECIFIED	Oral	0.3 Milligram	every 1 Day(s)	
SYNTHROID	Suspect	NOT SPECIFIED	Oral	0.05 Milligram	every 1 Day(s)	20.0 Day(s)
TIMOLOL	Concomitant	NOT SPECIFIED	Oral	2.5 Milligram	every 1 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Influenza like illness	v.17.0	
Rash maculo-papular	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000132052	0	1996-08-26	1996-08-26	MAH	SYN00796	Spontaneous	Pharmacist

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
64 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
SYNTHROID	Suspect	TABLET	Oral	100.0 Milligram	every 1 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest discomfort	v.17.0	
Decreased appetite	v.17.0	
Dyspnoea	v.17.0	
Fatigue	v.17.0	
Headache	v.17.0	
Malaise	v.17.0	
Nausea	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000132054	0	1996-06-15	1996-06-15	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
	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
ELTROXIN	Suspect	TABLET	Unknown			15.0 Year(s)

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal discomfort	v.17.0	
Asthenia	v.17.0	
Confusional state	v.17.0	
Dizziness	v.17.0	
Malaise	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000132057	0	1995-12-14	1995-12-14	MAH	CD95221	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
36 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
ELTROXIN	Suspect	TABLET	Oral	0.15 Microgram	every 1 Day(s)	2.0 Month(s)
LACTOSE	Suspect	NOT SPECIFIED				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Diarrhoea	v.17.0	
Dizziness	v.17.0	
Palpitations	v.17.0	
Pyrexia	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000132059	0	1995-12-14	1995-12-14	MAH	CD95210	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
56 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
BENADRYL	Drug used to treat AE	NOT SPECIFIED	Unknown			
ELTROXIN	Suspect	TABLET	Oral	0.05 Milligram	every 1 Day(s)	2.0 Day(s)
EXCIPIENTS	Suspect	NOT SPECIFIED				
SYNTHROID	Suspect	NOT SPECIFIED	Oral	0.1 Milligram	every 1 Day(s)	2.0 Week(s)

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain	v.17.0	
Agitation	v.17.0	
Rash	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000132406	0	2000-06-23	2000-07-21	MAH	SYN09500	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
	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
ACCUPRIL	Concomitant	TABLET	Oral			
ACEBUTOLOL HYDROCHLORIDE	Concomitant	TABLET	Oral			
PRAVACHOL	Concomitant	TABLET	Oral			
SYNTHROID	Suspect	NOT SPECIFIED	Oral	125.0 Microgram	2 every 1 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood thyroid stimulating hormone increased	v.17.0	
Myocardial infarction	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000132861	0	2000-07-12	2000-07-12	Hospital		Spontaneous	Physician

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
70 Years	Female			Death

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration
LITHIUM CARBONATE	Concomitant	NOT SPECIFIED	Oral	300.0 Milligram	2 every 1 Day(s)	
REQUIP	Suspect	TABLET	Oral	8.0 Milligram	3 every 1 Day(s)	
THYROXINE	Suspect	NOT SPECIFIED	Oral			
VERAPAMIL HYDROCHLORIDE INJECTION USP	Concomitant	LIQUID INTRAVENOUS	Oral	240.0 Milligram	every 1 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Cardiac arrest	v.17.0	
Microcytic anaemia	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000133391	0	2000-08-02	2000-08-02	MAH	PHBS2000CA04270	Study	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
55 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
CLONAZEPAM	Suspect	TABLET	Unknown			
CLOZARIL	Suspect	TABLET	Oral			148.0 Day(s)
ESTROGENS	Suspect	NOT SPECIFIED	Unknown			
LEVOTHYROXINE	Suspect	NOT SPECIFIED	Unknown			
SEROQUEL	Suspect	TABLET	Unknown			
SINGULAIR	Suspect	TABLET (CHEWABLE)	Unknown			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Convulsion	v.17.0	
Neutropenia	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000135317	0	2000-11-10	2000-11-15	MAH	SYN11600	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
32 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
ANAFRANIL	Drug used to treat AE	TABLET	Unknown			
SYNTHROID	Suspect	NOT SPECIFIED	Oral	125.0 Microgram	every 1 Day(s)	8.0 Year(s)

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.17.0	
Depression	v.17.0	
Fatigue	v.17.0	
Pulmonary fibrosis	v.17.0	
Sarcoidosis	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000140158	0	2001-06-29	2001-07-09	MAH	GBR003934	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
30 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
DIPHENHYDRAMINE	Drug used to treat AE	NOT SPECIFIED	Unknown			
SYNTHROID	Suspect	TABLET	Oral	100.0 Microgram	1 every 1 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dyspnoea	v.17.0	
Hypersensitivity	v.17.0	
Oedema	v.17.0	
Rash	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000140301	0	2001-06-26	2001-06-26	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
32 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
ELTROXIN	Suspect	TABLET	Unknown	50.0 Microgram	1 every 1 Day(s)	2.0 Day(s)

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest discomfort	v.17.0	
Pruritus	v.17.0	
Rash	v.17.0	
Throat tightness	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000140684	0	2001-07-13	2001-07-13	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
67 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
BENADRYL	Drug used to treat AE	NOT SPECIFIED	Unknown	25.0 Milligram	1 every 1 Day(s)	
CALCIUM CARBONATE	Concomitant	NOT SPECIFIED	Unknown			
CENTRUM TABLETS	Concomitant	TABLET	Unknown		1 every 1 Day(s)	
GOLD BOND	Drug used to treat AE	POWDER	Unknown			
GOLD BOND MEDICATED CREAM 28G	Drug used to treat AE	CREAM				
LANACANE CRM MEDICATION	Drug used to treat AE	CREAM	Unknown			
LECITHIN	Concomitant	NOT SPECIFIED	Unknown		every 1 Day(s)	
SYNTHROID	Suspect	TABLET	Unknown	1.0 Dosage forms	1 every 1 Day(s)	9.0 Year(s)
VITAMIN B12	Concomitant	NOT SPECIFIED	Unknown			
VITAMIN C	Concomitant	NOT SPECIFIED	Unknown			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pruritus	v.17.0	
Rash	v.17.0	
Urticaria	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000140726	0	2001-07-16	2001-07-16	MAH	CAN000923	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
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
SYNTHROID	Suspect	NOT SPECIFIED	Oral	75.0 Microgram	every 1 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.17.0	
Fatigue	v.17.0	
Insomnia	v.17.0	
Motion sickness	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000140728	0	2001-07-13	2001-07-13	Community		Special Access Program	Physician

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
71 Years	Male	152 Centimetres	63 Kilograms	Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration
FLUOROURACIL	Concomitant	NOT SPECIFIED	Intravenous (not otherwise specified)		Cyclical	
HEPARIN SODIUM INJECTION, USP	Drug used to treat AE	SOLUTION INTRAVENOUS	Unknown			
L-THYROXINE	Suspect	NOT SPECIFIED	Unknown	0.125 Milligram		3.0 Year(s)
THALIDOMIDE	Suspect	NOT SPECIFIED	Unknown	50.0 Milligram		60.0 Day(s)

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Deep vein thrombosis	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000140729	0	2001-07-16	2001-07-16	MAH	CAN000924	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	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
SYNTHROID	Suspect	NOT SPECIFIED	Oral			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Drug ineffective	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000140841	0	2001-07-20	2001-07-20	MAH	CAN00933	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
SYNTHROID	Suspect	NOT SPECIFIED	Oral	187.0 Microgram	every 1 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Bleeding time prolonged	v.17.0	
Contusion	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000141177	0	2001-08-03	2001-08-03	MAH	CAN000951	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
70 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
SYNTHROID	Suspect	NOT SPECIFIED	Oral	112.0 Microgram	every 1 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Depression	v.17.0	
Fatigue	v.17.0	
Suicidal ideation	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000141569	0	2001-06-28	2001-08-13	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
60 Years	Female	160 Centimetres	86 Kilograms	Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration
CALCIUM & MAGNESIUM	Concomitant	NOT SPECIFIED	Oral	800.0 Milligram	every 1 Day(s)	
INHIBACE	Concomitant	TABLET	Oral	10.0 Milligram	1 every 1 Day(s)	
MAGNESIUM	Concomitant	NOT SPECIFIED	Oral	250.0 Milligram	every 1 Day(s)	
MULTIVITAMINE(S)	Concomitant	NOT SPECIFIED	Oral	1.0 Dosage forms	every 1 Day(s)	
SYNTHROID	Suspect	NOT SPECIFIED	Oral	0.125 Milligram	every 1 Day(s)	
VITAMIN B12	Concomitant	INJECTION	Unknown		17 every 1 Year(s)	
VITAMIN C	Concomitant	NOT SPECIFIED	Oral	600.0 Milligram	every 1 Day(s)	
VITAMIN E	Concomitant	NOT SPECIFIED	Oral	400.0 IU (International Unit)	every 1 Day(s)	
ZINC	Concomitant	NOT SPECIFIED	Oral	25.0 Milligram	every 1 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Condition aggravated	v.17.0	
Drug ineffective	v.17.0	
Hypothyroidism	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000141926	0	2001-08-27	2001-08-27	Community		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
53 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
ELTROXIN	Suspect	TABLET	Oral	0.1 Milligram	1 every 1 Day(s)	3.0 Year(s)

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Diarrhoea	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000142074	0	2001-09-11	2001-09-14	MAH	CAN001000	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
SYNTHROID	Suspect	NOT SPECIFIED	Unknown			15.0 Year(s)

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.17.0	
Back pain	v.17.0	
Bone pain	v.17.0	
Dizziness	v.17.0	
Myocardial infarction	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000142741	0	2001-10-01	2002-06-24	MAH	CAN000995	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
73 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
ACEBUTOLOL HYDROCHLORIDE	Concomitant	TABLET	Oral			
ACETYLSALICYLIC ACID	Concomitant	TABLET	Oral	80.0 Milligram		
CLONIDINE	Concomitant	TABLET	Oral			
COLACE	Concomitant	NOT SPECIFIED	Oral			
DIGOXIN	Concomitant	TABLET	Oral	0.062 Milligram	every 2 Day(s)	
EPREX STERILE SOLUTION	Concomitant	SOLUTION INTRAVENOUS	Unknown			
FUROSEMIDE	Concomitant	TABLET	Oral	20.0 Milligram		
KAYEXALATE	Concomitant	POWDER	Unknown			
NORVASC	Concomitant	TABLET	Oral			
OMEPRAZOLE	Concomitant	NOT SPECIFIED	Oral	20.0 Milligram	every 1 Day(s)	
ROCALTROL	Concomitant	NOT SPECIFIED	Oral	0.025 Milligram	2 every 1 Week(s)	
SYNTHROID	Suspect	TABLET	Oral	0.2 Milligram	every 1 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood thyroid stimulating hormone increased	v.17.0	
Condition aggravated	v.17.0	
Constipation	v.17.0	
Drug ineffective	v.17.0	
Hypokinesia	v.17.0	
Hypothyroidism	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000144393	0	2001-12-10	2001-12-10	MAH	200100119900FU	Study	Physician

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
44 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
CARDURA	Concomitant	TABLET	Unknown			
EMPRACET	Drug used to treat AE	TABLET	Unknown			
EPREX STERILE SOLUTION	Concomitant	SOLUTION INTRAVENOUS	Unknown			
FERROUS SULPHATE	Concomitant	NOT SPECIFIED	Unknown			
MONOCOR	Concomitant	TABLET	Unknown			
MYCOPHENOLATE MOFETIL	Concomitant	CAPSULE	Unknown			
MYCOSTATIN	Concomitant	NOT SPECIFIED	Unknown			
PREDNISONE	Concomitant	NOT SPECIFIED	Unknown			
PROGRAF	Suspect	NOT SPECIFIED	Oral	11.0 Milligram	1 every 1 Day(s)	
SEPTRA	Concomitant	NOT SPECIFIED	Unknown			
SYNTHROID	Suspect	NOT SPECIFIED	Unknown			
ZANTAC	Concomitant	NOT SPECIFIED	Unknown			

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration
ZOVIRAX	Drug used to treat AE	NOT SPECIFIED	Intravenous (not otherwise specified)			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Herpes zoster	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000144682	0	2001-12-20	2001-12-20	MAH	E01MI021561	Spontaneous	Consumer Or Other Non Health Professional

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

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
ATIVAN	Suspect	NOT SPECIFIED	Unknown			
SEROQUEL	Suspect	TABLET	Unknown			
SYNTHROID	Suspect	NOT SPECIFIED	Unknown			
TRAZODONE	Suspect	TABLET	Unknown			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal distension	v.17.0	
Face oedema	v.17.0	
Fatigue	v.17.0	
Hypothyroidism	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000145125	0	2002-01-21	2002-01-21	MAH	GBR004932	Spontaneous	Other Health Professional

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
70 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
HYDROXYUREA	Suspect	NOT SPECIFIED	Oral			
SYNTHROID	Suspect	NOT SPECIFIED	Oral	25.0 Microgram	every 1 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Drug interaction	v.17.0	
Hyperthyroidism	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000145165	0	2001-01-04	2002-01-21	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
83 Years	Female	62 Centimetres	64 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
ALLOPURINOL	Suspect	TABLET	Unknown			
LABETALOL	Suspect	NOT SPECIFIED	Unknown			
LEVOTHYROXINE	Suspect	NOT SPECIFIED	Unknown			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthenia	v.17.0	
Dizziness	v.17.0	
Dysphagia	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000147433	0	2002-04-08	2002-04-08	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
41 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
CELEXA	Drug used to treat AE	TABLET	Unknown	10.0 Milligram	1 every 1 Day(s)	
SYNTHROID	Suspect	NOT SPECIFIED	Unknown	0.125 Milligram	every 1 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Depression	v.17.0	
Drug ineffective	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000147814	0	2002-04-24	2002-04-24	MAH	02P028019041800	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
39 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
CEFIZOX	Concomitant	POWDER FOR SOLUTION INTRAMUSCULAR	Intravenous (not otherwise specified)	2.0 Gram	2 every 1 Day(s)	10.0 Day(s)
CHOLESTYRAMINE	Concomitant	PACKAGE	Oral	2.0 Gram	3 every 1 Day(s)	
FUROSEMIDE	Concomitant	NOT SPECIFIED	Intravenous (not otherwise specified)	40.0 Milligram	2 every 1 Day(s)	11.0 Day(s)
HEPARIN SODIUM INJECTION, USP	Concomitant	SOLUTION INTRAVENOUS	Subcutaneous	5000.0 Units	2 every 1 Day(s)	11.0 Day(s)
INSULIN	Concomitant	NOT SPECIFIED	Subcutaneous		As required	
MIDAZOLAM INJECTION	Concomitant	SOLUTION INTRAMUSCULAR	Intravenous (not otherwise specified)		As required	3.0 Day(s)
MORPHINE	Concomitant	NOT SPECIFIED	Intravenous (not otherwise specified)			34.0 Day(s)

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration
PARACETAMOL	Concomitant	NOT SPECIFIED	Unknown	650.0 Milligram		
RANITIDINE	Concomitant	NOT SPECIFIED	Intravenous (not otherwise specified)	50.0 Milligram	3 every 1 Day(s)	11.0 Day(s)
SALBUTAMOL	Concomitant	NOT SPECIFIED	Inhalation		6 every 1 Day(s)	
SANDOSTATIN	Concomitant	SOLUTION INTRAVENOUS	Subcutaneous	100.0 Milligram	3 every 1 Day(s)	15.0 Day(s)
SYNTHROID	Suspect	NOT SPECIFIED	Other	0.1 Milligram	1 every 1 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Condition aggravated	v.17.0	
Hypothyroidism	v.17.0	
Malabsorption	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2014-07-13 - 09:53:00 AM
Initial Received Date:	1965-01-01 to 2014-03-31
Latest Received Date:	N/A
Total Number of Reports:	562 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
000148316	0	2002-05-08	2002-05-08	MAH	CD20021824	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			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
THYROXINE	Suspect	NOT SPECIFIED	Oral			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Palpitations	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000150571	0	2002-06-18	2002-06-18	MAH	E01ON01034	Study	Physician

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
76 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
AMIODARONE	Drug used to treat AE	NOT SPECIFIED	Unknown			
COMBIVENT	Concomitant	NOT SPECIFIED	Inhalation	2.0 Dosage forms	every 1 Day(s)	
CORDARONE	Suspect	NOT SPECIFIED	Oral	200.0 Milligram	every 1 Day(s)	3.0 Year(s)
DIGOXIN	Drug used to treat AE	NOT SPECIFIED	Unknown			
ELTROXIN	Suspect	TABLET	Oral			3.0 Year(s)
FLOVENT	Concomitant	NOT SPECIFIED	Inhalation	1.0 Dosage forms	2 every 1 Day(s)	
LASIX	Suspect	NOT SPECIFIED	Oral	80.0 Milligram	2 every 1 Day(s)	3.0 Year(s)
MORPHINE	Drug used to treat AE	NOT SPECIFIED	Unknown			
NITRO-DUR	Suspect	PATCH, EXTENDED RELEASE	Oral	0.4 Milligram	1 every 1 Day(s)	3.0 Year(s)
NOVASEN	Suspect	TABLET (ENTERIC-COATED)	Oral	325.0 Milligram	every 1 Day(s)	7.0 Year(s)
SEPTRA	Drug used to treat AE	NOT SPECIFIED	Unknown			
TYLENOL W CODEINE NO2 TAB	Drug used to treat AE	TABLET	Unknown			

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration
ZESTRIL	Suspect	TABLET	Oral	5.0 Milligram	1 every 1 Day(s)	
ZOLADEX	Suspect	IMPLANT	Subcutaneous	10.8 Milligram	4 every 1 Year(s)	346.0 Day(s)

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood creatine phosphokinase increased	v.17.0	
Blood lactate dehydrogenase increased	v.17.0	
Blood urea increased	v.17.0	
Burning sensation	v.17.0	
Cardiac failure congestive	v.17.0	
Dyspnoea	v.17.0	
Fatigue	v.17.0	
Fluid retention	v.17.0	
Oedema	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2014-07-13 - 09:53:00 AM
Initial Received Date:	1965-01-01 to 2014-03-31
Latest Received Date:	N/A
Total Number of Reports:	562 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
000152611	0	2002-07-30	2002-07-29	MAH	CD20022777	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
ELTROXIN	Suspect	TABLET	Unknown	300.0 Microgram	every 1 Day(s)	6.0 Year(s)

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain	v.17.0	
Anxiety	v.17.0	
Diarrhoea	v.17.0	
Weight decreased	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000152622	0	2002-07-30	2002-08-30	MAH	02P0280195906	Spontaneous	Other Health Professional

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
89 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
SYNTHROID	Suspect	NOT SPECIFIED	Unknown	0.1 Milligram		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood thyroid stimulating hormone increased	v.17.0	
Confusional state	v.17.0	
Lethargy	v.17.0	
Malaise	v.17.0	
Pain	v.17.0	
Sluggishness	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000152623	0	2002-07-30	2002-07-30	MAH	02P0280195911	Spontaneous	Other Health Professional

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
68 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
ELTROXIN	Suspect	TABLET	Oral	0.1 Milligram	1 every 1 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood thyroid stimulating hormone increased	v.17.0	
Fatigue	v.17.0	
Lethargy	v.17.0	
Malaise	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000153212	0	2002-08-16	2002-08-30	MAH	02P0280197573	Spontaneous	Other 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
59 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
COUMADIN	Drug used to treat AE	NOT SPECIFIED	Unknown	12.5 Milligram		
MERIDIA	Suspect	CAPSULE	Oral	10.0 Milligram	every 1 Day(s)	21.0 Day(s)
SYNTHROID	Suspect	NOT SPECIFIED	Oral	0.1 Milligram	1 every 1 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Atrial fibrillation	v.17.0	
Fatigue	v.17.0	
Heart rate increased	v.17.0	
Heart rate irregular	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000154127	0	1992-08-20	1992-08-20	Other		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			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
RIVOTRIL	Suspect	TABLET				
SYNTHROID	Suspect	NOT SPECIFIED				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Drug interaction	v.17.0	
Thyroxine increased	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2014-07-13 - 09:53:00 AM
Initial Received Date:	1965-01-01 to 2014-03-31
Latest Received Date:	N/A
Total Number of Reports:	562 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
000158426	0	2003-02-24	2003-02-24	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
60 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
COENZYME Q10	Suspect	NOT SPECIFIED	Unknown	60.0 Milligram	Once	
PREMARIN	Concomitant	NOT SPECIFIED	Unknown	0.625 Milligram		
PROMETRIUM - CAP 100MG	Concomitant	CAPSULE	Unknown			
SYNTHROID	Suspect	NOT SPECIFIED	Unknown	138.0 Microgram	every 1 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hyperkinesia	v.17.0	
Hyperthyroidism	v.17.0	
Insomnia	v.17.0	
Palpitations	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2014-07-13 - 09:53:00 AM
Initial Received Date:	1965-01-01 to 2014-03-31
Latest Received Date:	N/A
Total Number of Reports:	562 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
000159094	0	2003-03-11	2003-03-11	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
45 Years	Female		73 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
SYNTHROID	Suspect	NOT SPECIFIED	Oral	0.175 Milligram	every 1 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Constipation	v.17.0	
Dry skin	v.17.0	
Dysphonia	v.17.0	
Fatigue	v.17.0	
Headache	v.17.0	
Hypoaesthesia	v.17.0	
Insomnia	v.17.0	
Lethargy	v.17.0	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Menorrhagia	v.17.0	
Paraesthesia	v.17.0	
Therapeutic response decreased	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000160308	0	2003-04-22	2003-04-28	MAH	S2003CA00824	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			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
ELTROXIN	Suspect	TABLET	Unknown	0.05 Milligram	every 1 Day(s)	
ZELNORM	Suspect	TABLET	Oral			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Condition aggravated	v.17.0	
Irritable bowel syndrome	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000161636	0	2003-06-03	2003-06-03	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
2 Years	Female		10 Kilograms	Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration
CHARCOAL ACTIVATED	Drug used to treat AE	NOT SPECIFIED	Unknown			
IBUPROFEN	Drug used to treat AE	NOT SPECIFIED	Unknown	200.0 Milligram	Once	
SYNTHROID	Suspect	NOT SPECIFIED	Oral	150.0 Microgram		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Accidental overdose	v.17.0	
Tachycardia	v.17.0	
Thyroxine increased	v.17.0	
Tremor	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000164756	0	2003-10-01	2003-10-22	MAH	03P0280234586	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			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
SYNTHROID	Suspect	NOT SPECIFIED	Oral	50.0 Microgram	1 every 1 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dizziness	v.17.0	
Hypersensitivity	v.17.0	
Pruritus	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2014-07-13 - 09:53:00 AM
Initial Received Date:	1965-01-01 to 2014-03-31
Latest Received Date:	N/A
Total Number of Reports:	562 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
000164765	0	2003-10-08	2003-10-08	Community		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
83 Years	Female	165 Centimetres	68 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
ADRENALIN CHLORIDE SOL 1:1000	Drug used to treat AE	SOLUTION NASAL	Unknown	0.5 mL	Once	
CEFAZOLIN SODIUM NOVOPHARM	Suspect	POWDER FOR SOLUTION INTRAMUSCULAR	Intravenous (not otherwise specified)	1.0 Gram	3 every 1 Day(s)	1.0 Day(s)
COLACE	Concomitant	NOT SPECIFIED	Unknown	200.0 Milligram	1 every 1 Day(s)	
FRAGMIN	Concomitant	SOLUTION INTRAVENOUS	Subcutaneous	5000.0 Units	every 1 Day(s)	
HCTZ	Concomitant	NOT SPECIFIED	Unknown	12.5 Milligram	1 every 1 Day(s)	
HYDROCORTISONE	Drug used to treat AE	NOT SPECIFIED	Intravenous (not otherwise specified)	100.0 Milligram	4 every 1 Day(s)	
LACTULOSE SYRUP	Concomitant	SYRUP	Unknown	15.0 mL	2 every 1 Day(s)	
LEVOTHYROXINE	Suspect	NOT SPECIFIED	Unknown	0.088 Milligram	1 every 1 Day(s)	
RAMIPRIL	Concomitant	CAPSULE	Unknown	5.0 Milligram	1 every 1 Day(s)	
SALBUTAMOL	Drug used to treat AE	NOT SPECIFIED	Unknown		4 every 1 Day(s)	

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration
SENOKOT	Concomitant	NOT SPECIFIED	Unknown	2.0 Dosage forms	every 1 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anaphylactic reaction	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000164858	0	2003-10-06	2003-10-23	MAH	03P0280234811	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
44 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
CYTOMEL	Concomitant	NOT SPECIFIED	Oral	12.5	1 every 1 Day(s)	
SYNTHROID	Suspect	NOT SPECIFIED	Oral	50.0 Milligram	1 every 1 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.17.0	
Chest pain	v.17.0	
Dizziness	v.17.0	
Dyspepsia	v.17.0	
Dyspnoea	v.17.0	
Gait disturbance	v.17.0	
Generalised oedema	v.17.0	
Myalgia	v.17.0	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pain	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000165135	0	2003-10-21	2003-10-21	MAH	03P0280236485	Spontaneous	Other 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
70 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
ACETYLSALICYLIC ACID	Concomitant	NOT SPECIFIED	Unknown	325.0 Milligram		
FOLIC ACID	Concomitant	NOT SPECIFIED	Unknown			
LIPITOR	Concomitant	TABLET	Unknown			
METOPROLOL	Concomitant	NOT SPECIFIED	Unknown			
NITROLINGUAL SPRAY 0.4MG/EAM	Concomitant	METERED-DOSE (AEROSOL)	Unknown			
SYNTHROID	Suspect	NOT SPECIFIED	Oral	112.0 Microgram	1 every 1 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Myocardial infarction	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000165324	0	2003-12-16	2003-12-16	MAH	E03CV019502	Study	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
61 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
CALCIUM & MAGNESIUM	Concomitant	NOT SPECIFIED	Unknown			
CRESTOR	Suspect	TABLET	Oral	10.0 Milligram	every 1 Day(s)	3.0 Week(s)
ELTROXIN	Suspect	TABLET	Oral	0.1 Milligram	every 1 Day(s)	
MULTIVITAMINE(S)	Concomitant	NOT SPECIFIED	Unknown			
OMEGA 3-6-9	Concomitant	NOT SPECIFIED	Unknown			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hyperthyroidism	v.17.0	
Palpitations	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000165852	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
17 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
LEVOTHYROXINE	Suspect	NOT SPECIFIED	Unknown		Once	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypersensitivity	v.17.0	
Swelling	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000166688	0	2003-12-18	2004-06-07	MAH	CA20033711	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
56 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
ATIVAN	Concomitant	NOT SPECIFIED	Unknown			
CALCIUM	Concomitant	NOT SPECIFIED	Unknown			
DIGESTIVE	Concomitant	NOT SPECIFIED				
ELTROXIN	Suspect	TABLET	Oral	100.0 Microgram	every 2 Day(s)	2.0 Year(s)
HERBAL PREPARATION	Concomitant	NOT SPECIFIED				
MAGNESIUM	Concomitant	NOT SPECIFIED	Unknown			
VITAMINS	Concomitant	TABLET	Unknown			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.17.0	
Constipation	v.17.0	
Dry skin	v.17.0	
Dyspnoea	v.17.0	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Feeling cold	v.17.0	
Hyperhidrosis	v.17.0	
Sleep disorder	v.17.0	
Tachycardia	v.17.0	
Tremor	v.17.0	
Weight increased	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000168077	0	2004-02-19	2004-02-19	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
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
CYTOMEL	Concomitant	NOT SPECIFIED	Unknown			
ELTROXIN	Suspect	TABLET	Unknown	100.0 Microgram	every 1 Day(s)	7.0 Month(s)
LIOTHYRONINE	Suspect	TABLET	Unknown			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arrhythmia	v.17.0	
Chest pain	v.17.0	
Diarrhoea	v.17.0	
Headache	v.17.0	
Hyperhidrosis	v.17.0	
Irritability	v.17.0	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pyrexia	v.17.0	
Tremor	v.17.0	
Weight decreased	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000168182	0	2004-02-25	2004-02-25	MAH	03P0280239301	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
77 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
HERBAL PREPARATION	Drug used to treat AE	NOT SPECIFIED				
SYNTHROID	Suspect	NOT SPECIFIED	Oral	75.0 Microgram	1 every 1 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anxiety	v.17.0	
Decreased appetite	v.17.0	
Diarrhoea	v.17.0	
Lymphocytic leukaemia	v.17.0	
Nausea	v.17.0	
Oedema peripheral	v.17.0	
Thirst	v.17.0	
Vomiting	v.17.0	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Weight decreased	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000169309	0	2004-03-25	2004-08-11	Community		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
88 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
ARTHROTEC	Suspect	TABLET	Unknown		2 every 1 Day(s)	
ASA	Suspect	NOT SPECIFIED	Unknown		1 every 1 Day(s)	
COUMADIN	Suspect	NOT SPECIFIED	Unknown	3.5 Milligram	every 1 Day(s)	25.0 Day(s)
ELTROXIN	Suspect	TABLET	Unknown		1 every 1 Day(s)	
PACKED RED BLOOD CELLS	Drug used to treat AE	NOT SPECIFIED		3.0 Units		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Haemorrhage	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000169884	0	2004-04-14	2004-04-14	MAH	CD200400890	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
ELTROXIN	Suspect	TABLET	Oral			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Drug ineffective	v.17.0	
Malaise	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000170243	0	2004-04-23	2004-04-23	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
48 Years	Female		59 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
SYNTHROID	Suspect	NOT SPECIFIED	Unknown	50.0 Microgram		3.0 Day(s)

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Balance disorder	v.17.0	
Pruritus	v.17.0	
Rash	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000171350	0	2004-05-28	2004-05-28	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
82 Years	Female	165 Centimetres	60 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
BUDESONIDE	Concomitant	NOT SPECIFIED				
DIDROCAL-400MG(ETIDRONATE DISOD.)TAB AND 1250MG(CA CARB.)TAB(500MG CA)	Concomitant	KIT				
ERGOCALCIFEROL	Concomitant	NOT SPECIFIED				
HCTZ	Concomitant	NOT SPECIFIED				
LEVOTHYROXINE	Suspect	NOT SPECIFIED	Oral	300.0 Milligram	every 1 Day(s)	30.0 Year(s)
PARIET	Concomitant	TABLET (ENTERIC-COATED)				
VIOXX	Suspect	TABLET	Oral	25.0 Milligram	2 every 1 Day(s)	4.0 Day(s)

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Atrial fibrillation	v.17.0	
Dizziness	v.17.0	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Palpitations	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000171591	0	2004-06-08	2004-08-31	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
37 Years	Female	163 Centimetres	71 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
SYNTHROID	Suspect	TABLET	Unknown	0.025 Milligram	1 every 1 Day(s)	17.0 Month(s)
TYLENOL	Concomitant	NOT SPECIFIED			As required	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal pain	v.17.0	
Burning sensation	v.17.0	
Chest pain	v.17.0	
Headache	v.17.0	
Hypoaesthesia oral	v.17.0	
Malaise	v.17.0	
Nausea	v.17.0	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pain	v.17.0	
Palpitations	v.17.0	
Tremor	v.17.0	
Vertigo	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000171821	0	2004-06-15	2004-06-15	MAH	CA200401399	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
55 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
ELTROXIN	Suspect	TABLET	Oral	75.0 Microgram	every 1 Day(s)	18.0 Month(s)

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.17.0	6 Day(s)
Pharyngeal oedema	v.17.0	6 Day(s)

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000172341	0	2004-07-02	2004-08-03	MAH	04P0280264899	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
HYDROXYZINE	Drug used to treat AE	NOT SPECIFIED				
REACTINE	Drug used to treat AE	NOT SPECIFIED				
SYNTHROID	Suspect	NOT SPECIFIED	Oral	88.0 Microgram	1 every 1 Day(s)	
VENLAFAXINE	Concomitant	NOT SPECIFIED	Oral			
XENICAL 120MG CAPSULE	Concomitant	CAPSULE	Oral			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Depression	v.17.0	
Fatigue	v.17.0	
Urticaria	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000172434	0	2004-07-08	2005-02-10	MAH	2004007	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
75 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
ASPIRIN	Concomitant	NOT SPECIFIED				
CORTENEMA SUS 100MG/60ML	Suspect	ENEMA	Unknown			36.0 Day(s)
DESYREL	Suspect	TABLET				
GLUCOPHAGE	Concomitant	TABLET				
HYDROCHLOROTHIAZIDE	Suspect	TABLET				
INSULIN	Concomitant	NOT SPECIFIED				
MONOCOR	Concomitant	TABLET				
PLAVIX	Suspect	TABLET				
RISPERDAL	Suspect	NOT SPECIFIED				
SALOFALK	Suspect	TABLET (ENTERIC-COATED)	Oral	1000.0 Milligram	4 every 1 Day(s)	39.0 Day(s)
SYNTHROID	Suspect	NOT SPECIFIED				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Delirium	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2014-07-13 - 09:53:00 AM
Initial Received Date:	1965-01-01 to 2014-03-31
Latest Received Date:	N/A
Total Number of Reports:	562 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
000172686	0	2005-02-16	2005-02-16	MAH	CAP04000132	Spontaneous	Physician

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
80 Years	Female	158 Centimetres	69 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
ACTONEL	Suspect	TABLET	Oral	35.0 Milligram	1 every 1 Week(s)	184.0 Day(s)
ELTROXIN	Suspect	TABLET	Oral	0.1 Milligram	every 1 Day(s)	
LIPITOR	Suspect	TABLET	Oral	20.0 Milligram	every 1 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Alanine aminotransferase increased	v.17.0	
Arteriosclerosis	v.17.0	
Ascites	v.17.0	
Aspartate aminotransferase increased	v.17.0	
Diverticulum	v.17.0	
Generalised oedema	v.17.0	
Hepatic cirrhosis	v.17.0	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hepatic failure	v.17.0	
International normalised ratio increased	v.17.0	
Jaundice	v.17.0	
Pancreatitis necrotising	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000172973	0	2004-07-27	2004-07-27	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
3 Months	Male			Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration
CEPHALEXIN	Suspect	NOT SPECIFIED	Unknown			2.0 Month(s)
CORTISONE	Suspect	NOT SPECIFIED	Unknown			2.0 Month(s)
DDAVP	Suspect	NOT SPECIFIED	Unknown			2.0 Month(s)
SYNTHROID	Suspect	NOT SPECIFIED	Unknown			2.0 Month(s)

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Faeces discoloured	v.17.0	
Faeces discoloured	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000173662	0	2004-08-17	2004-08-17	MAH	04P0280269753	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
84 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
QUINAPRIL	Concomitant	TABLET				
SYNTHROID	Suspect	NOT SPECIFIED	Oral	12.5 Microgram	every 1 Day(s)	7.0 Day(s)

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Purpura	v.17.0	
Skin disorder	v.17.0	
Vasculitis	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000173771	0	2004-08-23	2004-08-23	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
59 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
ACIDOPHYLUS	Concomitant	NOT SPECIFIED				
GLUCOSAMINE	Concomitant	TABLET				
SYNTHROID	Suspect	NOT SPECIFIED	Unknown			
THYROID	Concomitant	NOT SPECIFIED				
VITAMIN C	Concomitant	NOT SPECIFIED				
VITAMIN E	Concomitant	NOT SPECIFIED				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Amnesia	v.17.0	
Hyperkinesia	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2014-07-13 - 09:53:00 AM
Initial Received Date:	1965-01-01 to 2014-03-31
Latest Received Date:	N/A
Total Number of Reports:	562 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
000175206	0	2004-10-07	2004-10-07	Community		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
79 Years	Male	184 Centimetres	109 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
BENADRYL	Drug used to treat AE	NOT SPECIFIED				
FUROSEMIDE	Concomitant	NOT SPECIFIED				
SYNTHROID	Suspect	TABLET	Unknown	12.5 Microgram	Once	
VALSARTAN	Concomitant	NOT SPECIFIED				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Angioedema	v.17.0	
Face oedema	v.17.0	
Flushing	v.17.0	
Pruritus	v.17.0	
Rash	v.17.0	
Tongue oedema	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000175392	0	2004-10-08	2004-10-08	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			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
ELTROXIN	Suspect	TABLET	Oral	0.1 Milligram	1 every 1 Day(s)	2.0 Day(s)

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000175644	0	2004-10-15	2004-10-15	MAH	04P0280276196	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			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
AVALIDE	Concomitant	TABLET				
BRIMONIDINE OPHTHALMIC	Concomitant	SOLUTION OPHTHALMIC	Ophthalmic			
CALCITONIN	Concomitant	NOT SPECIFIED				
CALCIUM	Concomitant	NOT SPECIFIED				
CORTISONE	Drug used to treat AE	NOT SPECIFIED				
EDECRIN	Concomitant	NOT SPECIFIED				
ERGOCALCIFEROL	Concomitant	NOT SPECIFIED				
GLYCERYL TRINITRATE	Concomitant	NOT SPECIFIED				
HYDROXYCHLOROQUINE	Concomitant	NOT SPECIFIED				
MAXIDEX	Concomitant	NOT SPECIFIED	Ophthalmic			
MULTIVITAMINS WITH MINERALS	Concomitant	NOT SPECIFIED				
OMEPRAZOLE	Concomitant	NOT SPECIFIED				

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration
SENNA FRUIT	Concomitant	NOT SPECIFIED				
SPIRONOLACTONE	Concomitant	TABLET				
SYNTHROID	Suspect	NOT SPECIFIED	Oral	125.0 Microgram		
WARFARIN	Concomitant	NOT SPECIFIED				
XALATAN	Concomitant	SOLUTION OPHTHALMIC				
ZOPICLONE	Concomitant	TABLET				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Gait disturbance	v.17.0	
Mobility decreased	v.17.0	
Pruritus	v.17.0	
Rash	v.17.0	
Speech disorder	v.17.0	
Urticaria	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000175799	0	2004-10-21	2004-10-21	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
46 Years	Female	164 Centimetres	54 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
SYNTHROID	Suspect	TABLET	Oral	100.0 Microgram	1 every 1 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.17.0	
Pain	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000177240	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
42 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
SYNTHROID	Suspect	NOT SPECIFIED	Unknown	9.0 Gram		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Intentional overdose	v.17.0	
Tachycardia	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000178138	0	2004-12-09	2004-12-09	MAH	S2004CA02547	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
72 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
ELTROXIN	Suspect	TABLET	Unknown	0.18 Dosage forms		
SYNTHROID	Concomitant	NOT SPECIFIED				
ZELNORM	Suspect	TABLET	Oral	6.0 Milligram	2 every 1 Day(s)	244.0 Day(s)

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Dry mouth	v.17.0	
Extrasystoles	v.17.0	
Palpitations	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000178644	0	2004-12-20	2004-12-20	MAH	04P0280282521	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
84 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
ALLOPURINOL	Concomitant	TABLET	Unknown			
FUROSEMIDE	Concomitant	NOT SPECIFIED	Unknown			
SYNTHROID	Suspect	NOT SPECIFIED	Oral		1 every 1 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood thyroid stimulating hormone increased	v.17.0	
Drug ineffective	v.17.0	
Hypothyroidism	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000179090	0	2005-01-05	2005-03-21	MAH	E05CV002001	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
	Male			Unknown

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	000179091

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration
ATACAND	Suspect	TABLET	Transplacental			
HYDROCHLOROTHIAZIDE	Suspect	TABLET	Transplacental			
PHOTOTHERAPY - SEE LIGHT	Drug used to treat AE	NOT SPECIFIED				
SYNTHROID	Suspect	NOT SPECIFIED	Transplacental			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Jaundice neonatal	v.17.0	
Skull malformation	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000179091	0	2005-01-05	2005-03-21	MAH	E04CV002249	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
26 Years	Female			Recovered/resolved with sequelae

Link / Duplicate Report Information

Record Type	Link AER** Number
Linked	000179090

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration
ATACAND	Suspect	TABLET	Oral	8.0 Milligram	1 every 1 Day(s)	
HYDROCHLOROTHIAZIDE	Suspect	TABLET	Oral	25.0 Milligram	1 every 1 Day(s)	
MATERNA	Concomitant	TABLET				
SYNTHROID	Suspect	NOT SPECIFIED	Unknown	88.0 Microgram	1 every 1 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Oligohydramnios	v.17.0	
Urinary tract malformation	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000179157	0	2004-12-30	2004-12-30	MAH	04P0280284442	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			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
SYNTHROID	Suspect	NOT SPECIFIED	Unknown	137.0 Microgram	every 1 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Drug ineffective	v.17.0	
Fatigue	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000179264	0	2005-01-10	2005-01-10	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			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
SYNTHROID	Suspect	NOT SPECIFIED	Unknown	112.0 Microgram	1 every 1 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Psychomotor hyperactivity	v.17.0	
Therapeutic response increased	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2014-07-13 - 09:53:00 AM
Initial Received Date:	1965-01-01 to 2014-03-31
Latest Received Date:	N/A
Total Number of Reports:	562 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
000180758	0	2005-03-16	2005-03-16	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
39 Years	Female	170 Centimetres	68 Kilograms	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
BENADRYL	Drug used to treat AE	NOT SPECIFIED				
SYNTHROID	Suspect	NOT SPECIFIED	Unknown			
THYROSENSE	Suspect	CAPSULE	Unknown	2.7 Dosage forms	every 1 Day(s)	3.0 Day(s)

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Drug interaction	v.17.0	
Dry skin	v.17.0	
Dyspnoea	v.17.0	
Nausea	v.17.0	
Pruritus	v.17.0	
Pyrexia	v.17.0	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Rash	v.17.0	
Skin burning sensation	v.17.0	
Throat tightness	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000180776	0	2005-03-01	2005-03-04	MAH	05P0280291301	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			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
INSULIN	Suspect	NOT SPECIFIED	Unknown			
SYNTHROID	Suspect	NOT SPECIFIED	Unknown	88.0 Microgram	1 every 1 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Chest pain	v.17.0	
Hypersensitivity	v.17.0	
Palpitations	v.17.0	
Pharyngeal oedema	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000181449	0	2005-02-17	2005-02-17	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
67 Years	Female	165 Centimetres	45 Kilograms	Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration
ELTROXIN	Suspect	TABLET	Oral	1.0 Dosage forms	every 1 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Diarrhoea	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000182264	0	2005-03-09	2005-03-09	MAH	05P0280292300	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
55 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
SYNTHROID	Suspect	NOT SPECIFIED	Unknown	125.0 Microgram	1 every 1 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Condition aggravated	v.17.0	
Drug ineffective	v.17.0	
Thyroid disorder	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000183125	0	2005-03-30	2005-03-30	MAH	2005AP000260	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
80 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
APO-WARFARIN	Suspect	TABLET	Oral		every 1 Day(s)	
CALCIUM & MAGNESIUM	Concomitant	NOT SPECIFIED				
CALTRATE 600 PLUS D - TABLET	Concomitant	TABLET				
FOSAMAX	Concomitant	NOT SPECIFIED				
SYNTHROID	Suspect	TABLET	Oral	88.0 Microgram	1 every 1 Day(s)	
VITAMIN C	Concomitant	NOT SPECIFIED				
VITAMIN E	Concomitant	NOT SPECIFIED				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Alopecia	v.17.0	
Contusion	v.17.0	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Drug interaction	v.17.0	
Dry skin	v.17.0	
Dysphonia	v.17.0	
Petechiae	v.17.0	
Prothrombin level decreased	v.17.0	
Prothrombin level increased	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000184047	0	2005-04-18	2005-04-18	MAH	CA200501057	Published	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
12 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
LEVOTHYROXINE	Suspect	NOT SPECIFIED	Unknown	75.0 Microgram	every 1 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Disturbance in attention	v.17.0	
Euphoric mood	v.17.0	
Hypomania	v.17.0	
Personality change	v.17.0	
Restlessness	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000184824	0	1996-12-16	1996-12-16	MAH	SYN01096	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			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
ELTROXIN	Drug used to treat AE	TABLET	Unknown	0.15 Microgram		
SYNTHROID	Suspect	NOT SPECIFIED	Oral	0.125 Microgram	every 1 Day(s)	4.5 Month(s)

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Therapeutic response decreased	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000185045	0	2005-05-10	2005-05-10	MAH	05P0280298842	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
70 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
SYNTHROID	Suspect	NOT SPECIFIED	Oral	200.0 Microgram	1 every 1 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Myocardial infarction	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000185382	0	2005-05-18	2005-05-18	Community		Spontaneous	Pharmacist

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
56 Years	Female	157 Centimetres	57 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
BENADRYL	Drug used to treat AE	NOT SPECIFIED				
SYNTHROID	Suspect	NOT SPECIFIED	Oral	100.0 Microgram		6.0 Day(s)

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Eyelid oedema	v.17.0	
Hypoaesthesia	v.17.0	
Pharyngeal oedema	v.17.0	
Pruritus	v.17.0	
Rash macular	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000185705	0	2005-05-24	2005-05-24	MAH	2005071762	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
88 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
ARTHROTEC	Suspect	TABLET	Unknown		2 every 1 Day(s)	
ASPIRIN	Suspect	NOT SPECIFIED	Unknown		1 every 1 Day(s)	
COUMADIN	Suspect	NOT SPECIFIED	Unknown	3.5 Milligram	1 every 1 Day(s)	
ELTROXIN	Suspect	TABLET	Unknown			
PACKED RED BLOOD CELLS	Drug used to treat AE	NOT SPECIFIED	Unknown			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Haemorrhage	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2014-07-13 - 09:53:00 AM
Initial Received Date:	1965-01-01 to 2014-03-31
Latest Received Date:	N/A
Total Number of Reports:	562 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
000186028	0	2005-06-07	2005-07-25	MAH	CA200501517	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
76 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
ALTACE	Concomitant	CAPSULE	Unknown			
ELTROXIN	Suspect	TABLET	Oral	50.0 Microgram	every 1 Day(s)	
LANOXIN	Suspect	NOT SPECIFIED	Unknown	0.25 Milligram	every 1 Day(s)	
LOPRESOR	Concomitant	NOT SPECIFIED	Unknown			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood pressure increased	v.17.0	
Heart rate increased	v.17.0	
Palpitations	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000186318	0	2005-06-15	2005-07-12	MAH	05P0280302494	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
65 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
SYNTHROID	Suspect	TABLET	Oral	125.0 Microgram	1 every 1 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood thyroid stimulating hormone increased	v.17.0	
Chest pain	v.17.0	
Dyspnoea	v.17.0	
Fatigue	v.17.0	
Hyperthyroidism	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000186749	0	1996-01-31	1996-01-31	MAH	SYN033/96	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

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
SYNTHROID	Suspect	NOT SPECIFIED	Unknown			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal distension	v.17.0	
Angina pectoris	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2014-07-13 - 09:53:00 AM
Initial Received Date:	1965-01-01 to 2014-03-31
Latest Received Date:	N/A
Total Number of Reports:	562 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
000187675	0	2005-07-13	2005-07-13	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
66 Years	Female	173 Centimetres	75 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
HYDROCHLOROTHIAZIDE	Concomitant	TABLET	Unknown			
LEVOTHYROXINE	Suspect	NOT SPECIFIED	Unknown	100.0 Microgram		
PREMARIN	Concomitant	NOT SPECIFIED	Unknown			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Malaise	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2014-07-13 - 09:53:00 AM
Initial Received Date:	1965-01-01 to 2014-03-31
Latest Received Date:	N/A
Total Number of Reports:	562 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
000187699	0	1997-06-11	1997-06-11	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
	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
ANTIHISTAMINIC DRUGS	Drug used to treat AE	NOT SPECIFIED				
ASTHMA MEDICATIONS	Concomitant	NOT SPECIFIED				
BECLOFORTE INHALER - AEM INH 250MCG/AEM	Concomitant	METERED-DOSE (AEROSOL)				
DYAZIDE TAB	Concomitant	TABLET				
FLOVENT	Concomitant	NOT SPECIFIED				
LEVOTHYROXINE	Suspect	NOT SPECIFIED	Oral			22.0 Day(s)
LOSEC	Concomitant	NOT SPECIFIED				
VENTOLIN	Drug used to treat AE	NOT SPECIFIED				

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Asthma	v.17.0	
Oedema	v.17.0	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Urticaria	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000187709	0	1997-05-09	1997-05-09	MAH	SYN06697	Spontaneous	Other 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
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
ELTROXIN	Drug used to treat AE	TABLET				
SYNTHROID	Suspect	NOT SPECIFIED	Oral	0.2 Milligram	every 1 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Fatigue	v.17.0	3 Day(s)
Headache	v.17.0	3 Day(s)
Palpitations	v.17.0	3 Day(s)
Tachycardia	v.17.0	3 Day(s)

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000187718	0	1997-01-23	1997-01-23	MAH	SYN01096	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
81 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
ELTROXIN	Drug used to treat AE	TABLET	Oral			
SYNTHROID	Suspect	NOT SPECIFIED	Oral	0.125 Milligram	every 1 Day(s)	5.0 Month(s)

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Therapeutic response decreased	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000188218	0	1996-01-19	1996-01-19	MAH	SYN00196	Spontaneous	Pharmacist

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
45 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
CORTISONE	Drug used to treat AE	CREAM				
SYNTHROID	Suspect	NOT SPECIFIED	Oral	0.112 Milligram	every 1 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Rash	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000188219	0	1996-01-22	1996-01-22	MAH	SYN00296	Spontaneous	Pharmacist

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
33 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
SYNTHROID	Suspect	NOT SPECIFIED	Oral	175.0 Microgram	every 1 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pharyngeal oedema	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000188220	0	1996-02-26	1996-02-26	MAH	SYN00496	Spontaneous	Pharmacist

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
70 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
SYNTHROID	Suspect	NOT SPECIFIED	Oral	0.75 Milligram	every 1 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hypersensitivity	v.17.0	
Sinusitis	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000188239	0	1996-05-09	1996-05-09	MAH	SYN00596	Spontaneous	Physician

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
42 Years	Female		59 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
ELTROXIN	Drug used to treat AE	TABLET				
SYNTHROID	Suspect	NOT SPECIFIED	Oral	50.0 Microgram	every 1 Day(s)	26.0 Day(s)

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Angioedema	v.17.0	
Skin exfoliation	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000188241	0	1996-06-11	1996-06-11	MAH	SYN00696	Spontaneous	Pharmacist

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
42 Years	Female		68 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
ANTIHISTAMINIC DRUGS	Drug used to treat AE	NOT SPECIFIED				
SYNTHROID	Suspect	NOT SPECIFIED	Oral	0.1 Milligram	every 1 Day(s)	4.0 Year(s)

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Pruritus	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000188242	0	1996-09-25	1996-09-25	MAH	Syn00896	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
45 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
ATROVENT	Concomitant	NOT SPECIFIED	Inhalation			
BECLOFORTE INHALER - AEM INH 250MCG/AEM	Concomitant	METERED-DOSE (AEROSOL)	Inhalation			
ELTROXIN	Drug used to treat AE	TABLET				
IBUPROFEN	Concomitant	NOT SPECIFIED				
RANITIDINE	Concomitant	NOT SPECIFIED				
SYNTHROID	Suspect	NOT SPECIFIED	Oral	0.1 Milligram	every 1 Day(s)	4.0 Year(s)

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Arthralgia	v.17.0	
Confusional state	v.17.0	
Disturbance in attention	v.17.0	
Myalgia	v.17.0	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Speech disorder	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000188244	0	1996-08-30	1996-08-30	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
74 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
LEVOTHYROXINE	Suspect	NOT SPECIFIED	Oral	0.1 Gram	2 every 1 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Rash	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000188245	0	1996-10-11	1996-10-11	MAH	SYN00996	Spontaneous	Pharmacist

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
49 Years	Female		59 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
SYNTHROID	Suspect	NOT SPECIFIED	Oral	88.0 Microgram	every 1 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Rash	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000188461	0	2005-09-09	2005-09-09	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
57 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
AZITHROMYCIN	Suspect	NOT SPECIFIED	Unknown			
CLONAZEPAM	Drug used to treat AE	TABLET	Unknown			
HYDROCHLOROTHIAZIDE/SPIRONOLACTONE	Concomitant	TABLET	Unknown			
LORAZEPAM	Drug used to treat AE	NOT SPECIFIED	Unknown			
MICARDIS	Suspect	TABLET	Unknown	80.0 Milligram	1 every 1 Day(s)	82.0 Day(s)
NORVASC	Suspect	TABLET	Unknown	2.5 Milligram	2 every 1 Day(s)	25.0 Day(s)
SYNTHROID	Suspect	NOT SPECIFIED	Unknown			
WARFARIN	Concomitant	NOT SPECIFIED	Unknown			

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Anxiety	v.17.0	
Blood thyroid stimulating hormone decreased	v.17.0	

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Drug interaction	v.17.0	
Dyspnoea	v.17.0	
Panic reaction	v.17.0	
Self-injurious ideation	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000188482	0	1995-07-16	1995-07-16	MAH	95CDN10000	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
64 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
CALCIUM TABLETS	Suspect	TABLET	Oral			
ELTROXIN	Suspect	TABLET	Oral	100.0 Microgram	every 1 Day(s)	
ESTRADERM TTS	Suspect	DISC (EXTENDED-RELEASE)	Transdermal	75.0 Microgram	every 1 Day(s)	
PROVERA	Suspect	TABLET	Oral	6.0 Milligram	every 1 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Breast tenderness	v.17.0	
Metrorrhagia	v.17.0	
Spleen disorder	v.17.0	
Thrombosis	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000189530	0	2005-08-23	2005-08-23	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
65 Years	Female	163 Centimetres	57 Kilograms	Unknown

Link / Duplicate Report Information

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

Product Information

Product Description	Health Product Role	Dosage Form	Route of Administration	Dose	Frequency	Therapy Duration
ELTROXIN	Suspect	TABLET	Unknown	0.05 Milligram	every 1 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal discomfort	v.17.0	
Malaise	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime:	2014-07-13 - 09:53:00 AM
Initial Received Date:	1965-01-01 to 2014-03-31
Latest Received Date:	N/A
Total Number of Reports:	562 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
000189860	0	2005-08-31	2005-09-19	MAH	05P0280308855	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
37 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
ANTACID	Drug used to treat AE	NOT SPECIFIED	Unknown			
PANTOLOC	Drug used to treat AE	TABLET (ENTERIC-COATED)	Unknown			
SYNTHROID	Suspect	NOT SPECIFIED	Unknown	175.0 Microgram		

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Abdominal discomfort	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000191654	0	2005-10-07	2005-10-07	MAH	05P0280312220	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
43 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
SYNTHROID	Suspect	NOT SPECIFIED	Oral	25.0 Microgram	1 every 1 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Blood creatine phosphokinase increased	v.17.0	
Confusional state	v.17.0	
Headache	v.17.0	
Peripheral coldness	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000191906	0	2005-10-13	2005-10-13	MAH	05P0280312665	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
34 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
SYNTHROID	Suspect	NOT SPECIFIED	Oral	137.0 Microgram	every 1 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Drug ineffective	v.17.0	
Drug level decreased	v.17.0	

Canada Vigilance
Summary of Reported Adverse Reactions

Report Runtime: 2014-07-13 - 09:53:00 AM
Initial Received Date: 1965-01-01 to 2014-03-31
Latest Received Date: N/A
Total Number of Reports: 562 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
000193140	0	1995-10-11	1995-10-11	MAH	SYN00295	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
SYNTHROID	Suspect	NOT SPECIFIED	Oral	125.0 Microgram	every 1 Day(s)	

Adverse Reaction Term Information

Adverse Reaction Term(s)	MedDRA Version	Reaction Duration
Hirsutism	v.17.0	