Canada Vigilance
Summary of Reported Adverse Reactions

Search Criteria

Report Runtime:	2013-06-06 - 2:42:14 PM
Range for Initial Receive Date:	1965-01-01 to 2013-02-28
Product Description:	YASMIN 28 YASMIN YASMIN 21 YASMIN (DROSPIRENONE, ETHINYL ESTRADIOL/NORETHINDRONE OR PLACEBO, ETHINYL ESTRADIOL) YASMIN (DROSPIRENONE/ETHINYLESTRADIOL) YASMIN (DROSPIRENONE W/ ETHINYLESTRADIOL) YASMIN (DROSPIRENONE W/ETHINYLESTRADIOL)
Product Role:	Suspect
Dosage Form:	-All-
Route of Administration:	-All-
Range for Age (years):	-All-
Patient Gender:	-All-
Case Serious?	-All-
Case Outcome:	Death
Report Source:	-All-
Reporter Type:	-All-
Domestic or Foreign:	Domestic

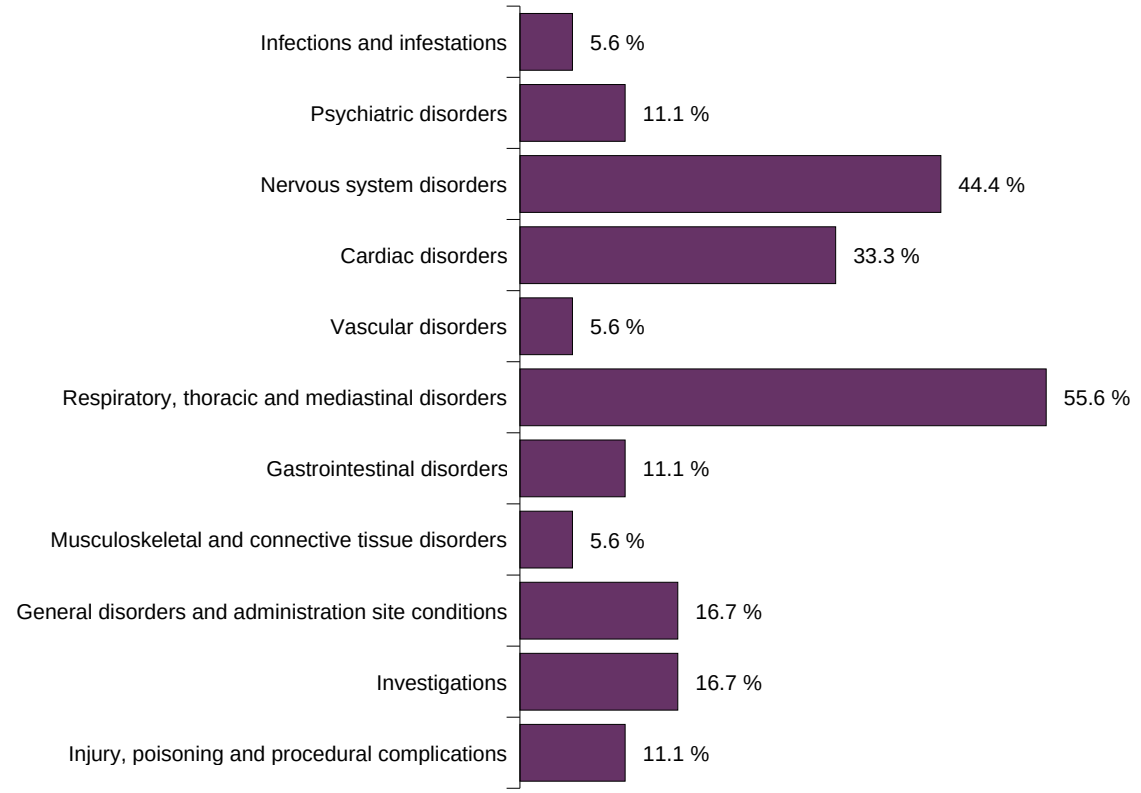
CAVEAT: This summary is based on information from adverse event reports submitted by health professionals and laypersons either directly to Health Canada or via market authorization holders. Each report represents the suspicion, opinion or observation of the individual reporter. The Canada Vigilance 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. (10/2007)

Health Canada Santé Canada

Report Runtime	2013-06-06 - 2:42:14 PM
Health Product:	PLACEBO, ETHINYL ESTRADIOL)
Initial date of receipt:	1965-01-01 to 2013-02-28
Total Number of Reports:	18 Reports

Canada Vigilance
Summary of Reported Adverse Reactions

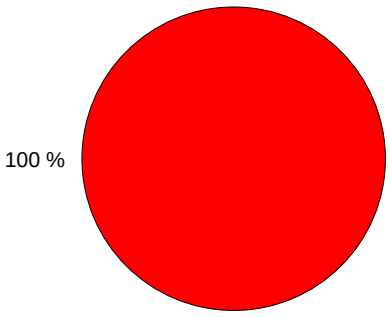
Occurrences by Primary System Organ Class (SOC)



Total No. of Reports: (Denominator)	18	Number of reports (percentage) with one or more reaction terms in the SOC(s) above

MedDRA V16.0

Serious Reports



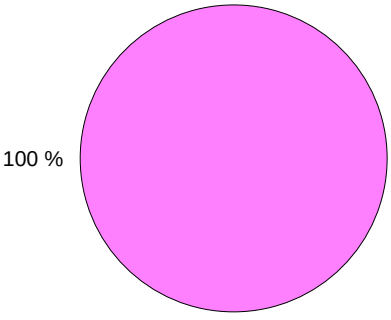
Yes	18

Reason for Seriousness

Death	18
LifeThreatening	1
Hospitalization Required	5
Disability	0
Congenital Anomaly	0
Other Medically Imp Condition	4

Total Number of Reports	18

Patient Summary



Female	18

Duplicate

Report Information

Aer No	Version No.	Initial Rec. Date	Latest Rec. Date	Report Source	MAH Number	Type of Report	Reporter Type
000321127	7	2009-03-31	2012-11-14	MAH	WAES0902CAN00119	Published	Physician

Record Type	Link Aer Number
Duplicate	000358593

Serious Report?	Death:	Disability:	Congenital Anomaly:
Yes	Yes		

Life Threatening:	Hospitalization:	Other Medically Imp Condition:
	Yes	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
14 Years	Female			Death

Product Information

Product Description	Product Role	Dosage Form	Route	Dosing	Frequency	Therapy Duration
GARDASIL	Suspect	SUSPENSION INTRAMUSCULAR	Parenteral	1 Dosage forms	Once	Once
YASMIN 28	Suspect	TABLET	Oral			78 Day(s)
INFLUENZA VACCINE	Concomitant	NOT SPECIFIED				

Reaction Information

MedDRA Preferred Term	MedDRA Version	Duration
Abasia	MedDRA V16.0	
Asthenia	MedDRA V16.0	
Basilar migraine	MedDRA V16.0	
Blood glucose increased	MedDRA V16.0	
Brain herniation	MedDRA V16.0	
Brain oedema	MedDRA V16.0	
Cardiac arrest	MedDRA V16.0	
Confusional state	MedDRA V16.0	
Dizziness postural	MedDRA V16.0	
Hypoxic-ischaemic encephalopathy	MedDRA V16.0	
Loss of consciousness	MedDRA V16.0	
Nausea	MedDRA V16.0	
Sudden death	MedDRA V16.0	
Syncope	MedDRA V16.0	
Vomiting	MedDRA V16.0	

Report Information

Aer No	Version No.	Initial Rec. Date	Latest Rec. Date	Report Source	MAH Number	Type of Report	Reporter Type
000326984	4	2009-07-16	2011-12-15	MAH	200926100NA	Spontaneous	Pharmacist

Record Type	Link Aer Number
Duplicate	000327129

Serious Report?	Death:	Disability:	Congenital Anomaly:
Yes	Yes		
	Life Threatening:	Hospitalization:	Other Medically Imp Condition:
			Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
26 Years	Female		135 Kilograms	Death

Product Information

Product Description	Product Role	Dosage Form	Route	Dosing	Frequency	Therapy Duration
YASMIN 28	Suspect	TABLET	Oral	1 Dosage forms	1 every 1 Day(s)	101 Day(s)
NAPROXEN	Concomitant	NOT SPECIFIED	Oral			
SYMBICORT TURBUHALER	Concomitant	POWDER	Unknown			
VENTOLIN	Concomitant	NOT SPECIFIED				

Reaction Information

MedDRA Preferred Term	MedDRA Version	Duration
Cardiac arrest	MedDRA V16.0	
Dyspnoea	MedDRA V16.0	
Hypoxia	MedDRA V16.0	
Loss of consciousness	MedDRA V16.0	
Pulmonary embolism	MedDRA V16.0	

Report Information

Aer No	Version No.	Initial Rec. Date	Latest Rec. Date	Report Source	MAH Number	Type of Report	Reporter Type
000327129	0	2009-07-21	2009-07-21	Community		Spontaneous	Other Health Professional

Record Type	Link Aer Number
Duplicate	000326984

Serious Report?	Death:	Disability:	Congenital Anomaly:
Yes	Yes		
	Life Threatening:	**Hospitalization:**	**Other Medically Imp Condition:**

Patient Information

Age	Gender	Height	Weight	Report Outcome
26 Years	Female	170 Centimetres	298 Pounds	Death

Product Information

Product Description	Product Role	Dosage Form	Route	Dosing	Frequency	Therapy Duration
YASMIN 28	Suspect	TABLET	Oral	1 Dosage forms	1 every 1 Day(s)	101 Day(s)
NAPROXEN	Concomitant	NOT SPECIFIED	Unknown			
SYMBICORT TURBUHALER	Concomitant	POWDER	Unknown			

Reaction Information

MedDRA Preferred Term	MedDRA Version	Duration
Pulmonary embolism	MedDRA V16.0	

Report Information

Aer No	Version No.	Initial Rec. Date	Latest Rec. Date	Report Source	MAH Number	Type of Report	Reporter Type
000358593	0	2010-12-24	2010-12-24	MAH	2010004848	Spontaneous	Other Health Professional

Record Type	Link Aer Number
Duplicate	000321127

Serious Report?	Death:	Disability:	Congenital Anomaly:
Yes	Yes		
	Life Threatening:	**Hospitalization:**	**Other Medically Imp Condition:**
		Yes	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
14 Years	Female			Death

Product Information

Product Description	Product Role	Dosage Form	Route	Dosing	Frequency	Therapy Duration
GARDASIL	Suspect	SUSPENSION INTRAMUSCULAR	Subcutaneous			1 Day(s)
GARDASIL	Suspect	SUSPENSION INTRAMUSCULAR	Unknown			1 Day(s)
YASMIN 21	Suspect	TABLET	Unknown			61 Day(s)
INFLUENZA VACCINE	Concomitant	NOT SPECIFIED	Unknown			

Reaction Information

MedDRA Preferred Term	MedDRA Version	Duration
Abasia	MedDRA V16.0	
Asthenia	MedDRA V16.0	
Basilar migraine	MedDRA V16.0	
Blood glucose increased	MedDRA V16.0	
Cardiac arrest	MedDRA V16.0	
Confusional state	MedDRA V16.0	
Dizziness postural	MedDRA V16.0	
Drowning	MedDRA V16.0	
Loss of consciousness	MedDRA V16.0	
Nausea	MedDRA V16.0	
Syncope	MedDRA V16.0	
Vomiting	MedDRA V16.0	

Report Information

Aer No	Version No.	Initial Rec. Date	Latest Rec. Date	Report Source	MAH Number	Type of Report	Reporter Type
000442802	0	2012-06-12	2012-06-12	Community		Spontaneous	Physician

Record Type	Link Aer Number
Duplicate	000446210

Serious Report?	Death:	Disability:	Congenital Anomaly:
Yes	Yes		
	Life Threatening:	**Hospitalization:**	**Other Medically Imp Condition:**

Patient Information

Age	Gender	Height	Weight	Report Outcome
32 Years	Female			Death

Product Information

Product Description	Product Role	Dosage Form	Route	Dosing	Frequency	Therapy Duration
YASMIN 28	Suspect	TABLET	Unknown			
ASTHMA MEDICATIONS	Concomitant	NOT SPECIFIED				

Reaction Information

MedDRA Preferred Term	MedDRA Version	Duration
Cardiac arrest	MedDRA V16.0	
Ventricular fibrillation	MedDRA V16.0	

Report Information

Aer No	Version No.	Initial Rec. Date	Latest Rec. Date	Report Source	MAH Number	Type of Report	Reporter Type
000446210	0	2012-06-25	2012-06-25	MAH	2012058573	Spontaneous	Lawyer

Record Type	Link Aer Number
Duplicate	000442802

Serious Report?	Death:	Disability:	Congenital Anomaly:
Yes	Yes		
	Life Threatening:	**Hospitalization:**	**Other Medically Imp Condition:**
		Yes	

Patient Information

Age	Gender	Height	Weight	Report Outcome
32 Years	Female			Death

Product Information

Product Description	Product Role	Dosage Form	Route	Dosing	Frequency	Therapy Duration
YASMIN 21	Suspect	TABLET	Unknown			
ASTHMA MEDICATIONS	Concomitant	NOT SPECIFIED				

Reaction Information

MedDRA Preferred Term	MedDRA Version	Duration
Arrhythmia	MedDRA V16.0	
Cardiac arrest	MedDRA V16.0	

No Duplicate or Linked Reports

Report Information

Aer No	Version No.	Initial Rec. Date	Latest Rec. Date	Report Source	MAH Number	Type of Report	Reporter Type
000224355	0	2007-12-03	2007-12-03	MAH	CA2007039345	Spontaneous	Physician

Record Type	Link Aer Number
No Duplicate or Linked Reports	

Serious Report?	Death:	Disability:	Congenital Anomaly:
Yes	Yes		
	Life Threatening:	**Hospitalization:**	**Other Medically Imp Condition:**

Patient Information

Age	Gender	Height	Weight	Report Outcome
23 Years	Female			Death

Product Information

Product Description	Product Role	Dosage Form	Route	Dosing	Frequency	Therapy Duration
YASMIN 28	Suspect	TABLET	Oral			91 Day(s)

Reaction Information

MedDRA Preferred Term	MedDRA Version	Duration
Convulsion	MedDRA V16.0	
Dyspnoea	MedDRA V16.0	
Loss of consciousness	MedDRA V16.0	
Pulmonary embolism	MedDRA V16.0	

Report Information

Aer No	Version No.	Initial Rec. Date	Latest Rec. Date	Report Source	MAH Number	Type of Report	Reporter Type
000302699	0	2008-04-30	2008-04-30	Community	200910268NA	Spontaneous	Other Health Professional

Record Type	Link Aer Number
No Duplicate or Linked Reports	

Serious Report?	Death:	Yes	Disability:		Congenital Anomaly:	
Yes	Life Threatening:		Hospitalization:		Other Medically Imp Condition:	

Patient Information

Age	Gender	Height	Weight	Report Outcome
23 Years	Female	173 Centimetres	124 Kilograms	Death

Product Information

Product Description	Product Role	Dosage Form	Route	Dosing	Frequency	Therapy Duration
YASMIN 28	Suspect	TABLET	Oral	1 Dosage forms	1 every 1 Day(s)	

Reaction Information

MedDRA Preferred Term	MedDRA Version	Duration
Cardiac arrest	MedDRA V16.0	
Chest pain	MedDRA V16.0	
Circulatory collapse	MedDRA V16.0	
Computerised tomogram abnormal	MedDRA V16.0	
Dyspnoea	MedDRA V16.0	
Pain in extremity	MedDRA V16.0	
Pulmonary embolism	MedDRA V16.0	

Report Information

Aer No	Version No.	Initial Rec. Date	Latest Rec. Date	Report Source	MAH Number	Type of Report	Reporter Type
000333038	3	2009-11-12	2009-12-31	MAH	200938680NA	Spontaneous	Other Health Professional

Record Type	Link Aer Number
No Duplicate or Linked Reports	

Serious Report?	Death:	Yes	Disability:		Congenital Anomaly:	
Yes	Life Threatening:		Hospitalization:		Other Medically Imp Condition:	

Patient Information

Age	Gender	Height	Weight	Report Outcome
15 Years	Female			Death

Product Information

Product Description	Product Role	Dosage Form	Route	Dosing	Frequency	Therapy Duration
YASMIN 28	Suspect	TABLET	Oral	1 Dosage forms	1 every 1 Day(s)	

Reaction Information

MedDRA Preferred Term	MedDRA Version	Duration
Pulmonary embolism	MedDRA V16.0	

Report Information

Aer No	Version No.	Initial Rec. Date	Latest Rec. Date	Report Source	MAH Number	Type of Report	Reporter Type
000347628	1	2010-07-19	2010-09-24	MAH	201027827NA	Spontaneous	Physician

Record Type	Link Aer Number
No Duplicate or Linked Reports	

Serious Report?	Death:	Yes	Disability:		Congenital Anomaly:	
Yes	Life Threatening:		Hospitalization:		Other Medically Imp Condition:	

Patient Information

Age	Gender	Height	Weight	Report Outcome
19 Years	Female			Death

Product Information

Product Description	Product Role	Dosage Form	Route	Dosing	Frequency	Therapy Duration
YASMIN 28	Suspect	TABLET	Oral			

Reaction Information

MedDRA Preferred Term	MedDRA Version	Duration
Pulmonary embolism	MedDRA V16.0	

Report Information

Aer No	Version No.	Initial Rec. Date	Latest Rec. Date	Report Source	MAH Number	Type of Report	Reporter Type
000360420	0	2011-01-25	2011-01-25	Hospital	2011058892	Spontaneous	Pharmacist

Record Type	Link Aer Number
No Duplicate or Linked Reports	

Serious Report?	Death:	Disability:	Congenital Anomaly:
Yes	Yes		
	Life Threatening:	**Hospitalization:**	**Other Medically Imp Condition:**

Patient Information

Age	Gender	Height	Weight	Report Outcome
18 Years	Female	152 Centimetres	80 Kilograms	Death

Product Information

Product Description	Product Role	Dosage Form	Route	Dosing	Frequency	Therapy Duration
CONCERTA	Suspect	TABLET (EXTENDED-RELEASE)	Oral	54 Milligram	1 every 1 Day(s)	
YASMIN 28	Suspect	TABLET	Oral	1 Dosage forms	1 every 1 Day(s)	
MERREM	Concomitant	POWDER FOR SOLUTION INTRAVENOUS	Unknown			
NIMBEX	Concomitant	LIQUID INTRAVENOUS	Unknown			
PIPERACILLIN/TAZOBACTAM	Concomitant	NOT SPECIFIED	Unknown			
PRECEDEX	Concomitant	SOLUTION INTRAVENOUS	Unknown			
RANITIDINE	Concomitant	NOT SPECIFIED	Unknown			
SENNOSIDES	Concomitant	NOT SPECIFIED	Unknown			
VANCOMYCIN	Concomitant	NOT SPECIFIED	Unknown			

Reaction Information

MedDRA Preferred Term	MedDRA Version	Duration
Cerebral haemorrhage	MedDRA V16.0	
Cerebral venous thrombosis	MedDRA V16.0	

Report Information

Aer No	Version No.	Initial Rec. Date	Latest Rec. Date	Report Source	MAH Number	Type of Report	Reporter Type
000364889	1	2011-03-24	2011-04-07	MAH	2011021636	Spontaneous	Physician

Record Type	Link Aer Number
No Duplicate or Linked Reports	

Serious Report?	Death:	Yes	Disability:		Congenital Anomaly:	
Yes	Life Threatening:		Hospitalization:		Other Medically Imp Condition:	

Patient Information

Age	Gender	Height	Weight	Report Outcome
19 Years	Female			Death

Product Information

Product Description	Product Role	Dosage Form	Route	Dosing	Frequency	Therapy Duration
YASMIN 21	Suspect	TABLET	Unknown			

Reaction Information

MedDRA Preferred Term	MedDRA Version	Duration
Intracranial aneurysm	MedDRA V16.0	

Report Information

Aer No	Version No.	Initial Rec. Date	Latest Rec. Date	Report Source	MAH Number	Type of Report	Reporter Type
000389720	0	2011-11-24	2011-11-24	MAH	2011111177	Spontaneous	Physician

Record Type	Link Aer Number
No Duplicate or Linked Reports	

Serious Report?	Death:	Yes	Disability:		Congenital Anomaly:	
Yes	Life Threatening:		Hospitalization:	Yes	Other Medically Imp Condition:	

Patient Information

Age	Gender	Height	Weight	Report Outcome
40 Years	Female			Death

Product Information

Product Description	Product Role	Dosage Form	Route	Dosing	Frequency	Therapy Duration
YASMIN 21	Suspect	TABLET	Unknown			

Reaction Information

MedDRA Preferred Term	MedDRA Version	Duration
Ankle fracture	MedDRA V16.0	
Pulmonary embolism	MedDRA V16.0	

Report Information

Aer No	Version No.	Initial Rec. Date	Latest Rec. Date	Report Source	MAH Number	Type of Report	Reporter Type
000446211	0	2012-06-25	2012-06-25	MAH	2012058576	Spontaneous	Lawyer

Record Type	Link Aer Number
No Duplicate or Linked Reports	

Serious Report?	Death:	Yes	Disability:		Congenital Anomaly:	
Yes	Life Threatening:		Hospitalization:		Other Medically Imp Condition:	

Patient Information

Age	Gender	Height	Weight	Report Outcome
15 Years	Female			Death

Product Information

Product Description	Product Role	Dosage Form	Route	Dosing	Frequency	Therapy Duration
YASMIN 21	Suspect	TABLET	Unknown			

Reaction Information

MedDRA Preferred Term	MedDRA Version	Duration
Syncope	MedDRA V16.0	

Report Information

Aer No	Version No.	Initial Rec. Date	Latest Rec. Date	Report Source	MAH Number	Type of Report	Reporter Type
000461530	0	2012-08-29	2012-08-29	MAH	CAJNJFOC20120812058(	Spontaneous	Consumer Or Other Non Health Professional

Record Type	Link Aer Number
No Duplicate or Linked Reports	

Serious Report?	Death:	Yes	Disability:		Congenital Anomaly:	
Yes	Life Threatening:		Hospitalization:		Other Medically Imp Condition:	

Patient Information

Age	Gender	Height	Weight	Report Outcome
18 Years	Female			Death

Product Information

Product Description	Product Role	Dosage Form	Route	Dosing	Frequency	Therapy Duration
CONCERTA	Suspect	TABLET (EXTENDED-RELEASE)	Oral			
YASMIN 28	Suspect	TABLET	Unknown			

Reaction Information

MedDRA Preferred Term	MedDRA Version	Duration
Cerebral venous thrombosis	MedDRA V16.0	

Report Information

Aer No	Version No.	Initial Rec. Date	Latest Rec. Date	Report Source	MAH Number	Type of Report	Reporter Type
000497817	0	2013-02-07	2013-02-07	Community		Spontaneous	Consumer Or Other Non Health Professional

Record Type	Link Aer Number
No Duplicate or Linked Reports	

Serious Report?	Death:	Disability:	Congenital Anomaly:
Yes	Yes		

Life Threatening:	Hospitalization:	Other Medically Imp Condition:
Yes	Yes	Yes

Patient Information

Age	Gender	Height	Weight	Report Outcome
36 Years	Female	157 Centimetres	300 Pounds	Death

Product Information

Product Description	Product Role	Dosage Form	Route	Dosing	Frequency	Therapy Duration
YASMIN 28	Suspect	TABLET	Oral		1 every 1 Day(s)	8 Week(s)

Reaction Information

MedDRA Preferred Term	MedDRA Version	Duration
Influenza	MedDRA V16.0	
Pulmonary embolism	MedDRA V16.0	

Report Information

Aer No	Version No.	Initial Rec. Date	Latest Rec. Date	Report Source	MAH Number	Type of Report	Reporter Type
000499352	0	2013-02-13	2013-02-13	Community		Spontaneous	Consumer Or Other Non Health Professional

Record Type	Link Aer Number
No Duplicate or Linked Reports	

Serious Report?	Death:	Disability:	Congenital Anomaly:
Yes	Yes		

Life Threatening:	Hospitalization:	Other Medically Imp Condition:

Patient Information

Age	Gender	Height	Weight	Report Outcome
36 Years	Female		298 Pounds	Death

Product Information

Product Description	Product Role	Dosage Form	Route	Dosing	Frequency	Therapy Duration
YASMIN 28	Suspect	TABLET	Oral	1 Dosage forms	1 every 1 Day(s)	37 Day(s)
ELTROXIN	Concomitant	TABLET				

Reaction Information

MedDRA Preferred Term	MedDRA Version	Duration
Pulmonary embolism	MedDRA V16.0	

Report Information

Aer No	Version No.	Initial Rec. Date	Latest Rec. Date	Report Source	MAH Number	Type of Report	Reporter Type
000501984	0	2013-02-14	2013-02-14	MAH	2013013398	Spontaneous	Consumer Or Other Non Health Professional

Record Type	Link Aer Number
No Duplicate or Linked Reports	

Serious Report?	Death:	Disability:	Congenital Anomaly:
Yes	Yes		
	Life Threatening:	Hospitalization:	Other Medically Imp Condition:

Patient Information

Age	Gender	Height	Weight	Report Outcome
	Female			Death

Product Information

Product Description	Product Role	Dosage Form	Route	Dosing	Frequency	Therapy Duration
YASMIN 28	Suspect	TABLET	Oral			

Reaction Information

MedDRA Preferred Term	MedDRA Version	Duration
Pulmonary embolism	MedDRA V16.0	