Canada Vigilance
Summary of Reported Adverse Reactions

Search Criteria

Report Runtime:	2013-06-06 - 2:48:12 PM
Range for Initial Receive Date:	1965-01-01 to 2013-02-28
Product Description:	YAZ 28 YAZ YAZ (DROSPIRENONE + ETHINYLESTRADIOL) YAZ (DROSPIRENONE+ETHINYLESTRADIOL) YAZ (DROSPIRENONE, ETHINYL ESTRADIOL/NORETHINDRONE OR PLACEBO, ETHINYL ESTRADIOL)
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

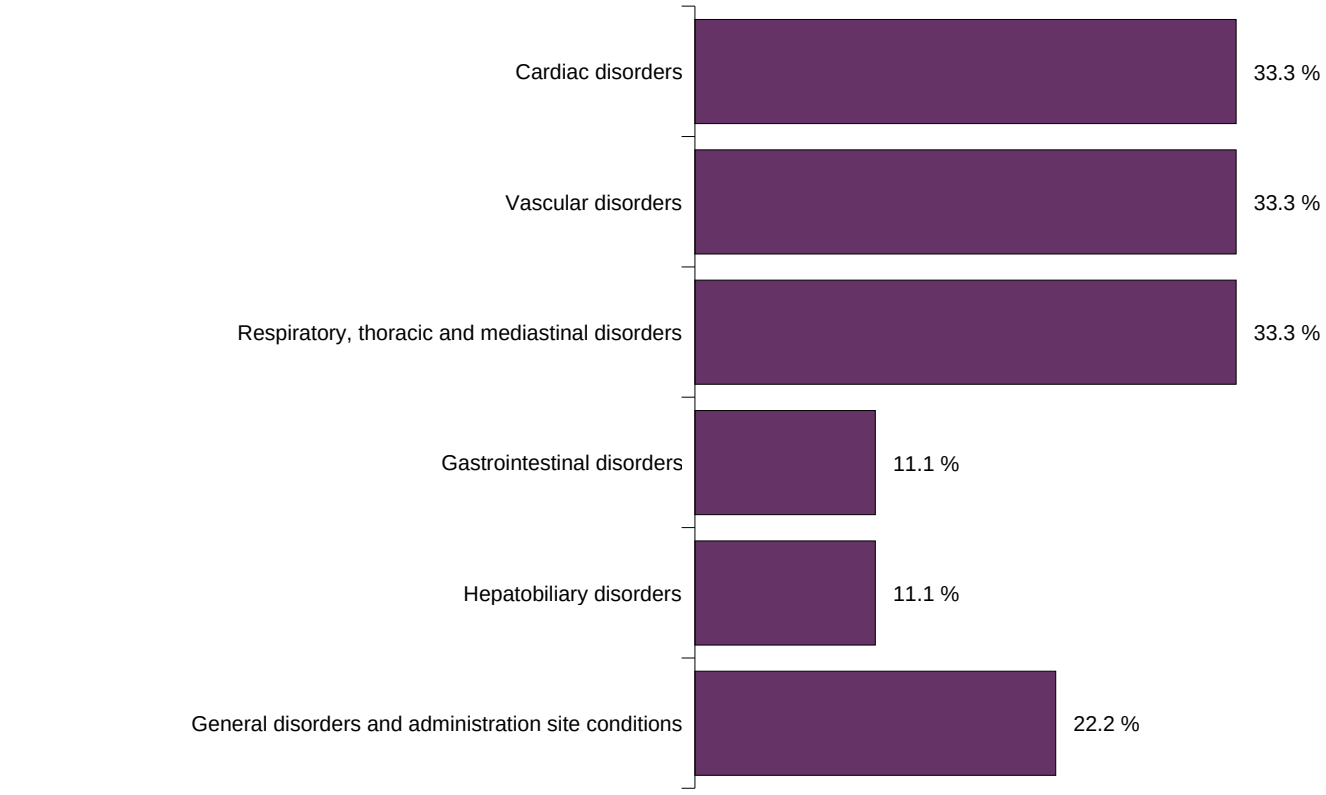
CAVEAT: This summary is based on information from adverse event reports submitted by health professionals and laypersons either directly to Health Canada or via market authorization holders. Each report represents the suspicion, opinion or observation of the individual reporter. The Canada Vigilance 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 - 2:48:12 PM
Health Product:	RENONE + ETHINYLESTRADIOL)
Initial date of receipt:	1965-01-01 to 2013-02-28
Total Number of Reports:	9 Reports

Canada Vigilance
Summary of Reported Adverse Reactions

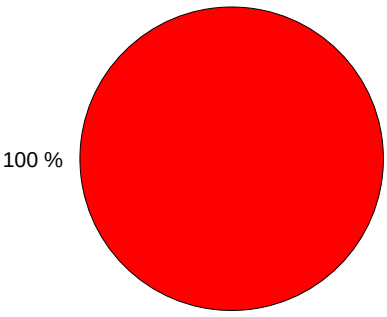
Occurrences by Primary System Organ Class (SOC)



Total No. of Reports: (Denominator)	9	Number of reports (percentage) with one or more reaction terms in the SOC(s) above

MedDRA V16.0

Serious Reports



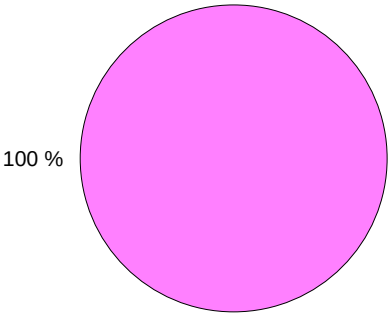
Yes	9

Reason for Seriousness

Death	9
LifeThreatening	1
Hospitalization Required	1
Disability	0
Congenital Anomaly	0
Other Medically Imp Condition	0

Total Number of Reports	9

Patient Summary



Female	9

Duplicate

Report Information

Aer No	Version No.	Initial Rec. Date	Latest Rec. Date	Report Source	MAH Number	Type of Report	Reporter Type
000366016	0	2011-04-07	2011-04-07	Community	2011064404	Spontaneous	Other Health Professional

Record Type	Link Aer Number
Duplicate	000366958

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
44 Years	Female			Death

Product Information

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

Reaction Information

MedDRA Preferred Term	MedDRA Version	Duration
Abdominal pain	MedDRA V16.0	
Asthenia	MedDRA V16.0	
Cardiac arrest	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
000366958	0	2011-04-18	2011-04-18	MAH	2011030181	Spontaneous	Other Health Professional

Record Type	Link Aer Number
Duplicate	000366016

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

Patient Information

Age	Gender	Height	Weight	Report Outcome
44 Years	Female			Death

Product Information

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

Reaction Information

MedDRA Preferred Term	MedDRA Version	Duration
Cardio-respiratory arrest	MedDRA V16.0	
Pulmonary embolism	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
000346138	1	2010-06-23	2010-06-24	MAH	201025756NA	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
	Female			Death

Product Information

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

Reaction Information

MedDRA Preferred Term	MedDRA Version	Duration
Death	MedDRA V16.0	

Report Information

Aer No	Version No.	Initial Rec. Date	Latest Rec. Date	Report Source	MAH Number	Type of Report	Reporter Type
000346426	1	2010-06-28	2010-07-21	MAH	201025999NA	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
	Female			Death

Product Information

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

Reaction Information

MedDRA Preferred Term	MedDRA Version	Duration
Cardiovascular disorder	MedDRA V16.0	

Report Information

Aer No	Version No.	Initial Rec. Date	Latest Rec. Date	Report Source	MAH Number	Type of Report	Reporter Type
000357879	3	2010-12-15	2011-04-07	MAH	2010003190	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
24 Years	Female	70 Inches	149 Kilograms	Death

Product Information

Product Description	Product Role	Dosage Form	Route	Dosing	Frequency	Therapy Duration
YAZ	Suspect	TABLET	Unknown			
SYMBICORT TURBUHALER	Concomitant	POWDER	Unknown			

Reaction Information

MedDRA Preferred Term	MedDRA Version	Duration
Embolism venous	MedDRA V16.0	

Report Information

Aer No	Version No.	Initial Rec. Date	Latest Rec. Date	Report Source	MAH Number	Type of Report	Reporter Type
000361949	0	2011-02-14	2011-02-14	MAH	2011009947	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
20 Years	Female			Death

Product Information

Product Description	Product Role	Dosage Form	Route	Dosing	Frequency	Therapy Duration
YAZ	Suspect	TABLET	Unknown			365 Day(s)

Reaction Information

MedDRA Preferred Term	MedDRA Version	Duration
Hepatic failure	MedDRA V16.0	

Report Information

Aer No	Version No.	Initial Rec. Date	Latest Rec. Date	Report Source	MAH Number	Type of Report	Reporter Type
000365424	0	2011-03-31	2011-03-31	MAH	2011025670	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
16 Years	Female			Death

Product Information

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

Reaction Information

MedDRA Preferred Term	MedDRA Version	Duration
Embolism venous	MedDRA V16.0	

Report Information

Aer No	Version No.	Initial Rec. Date	Latest Rec. Date	Report Source	MAH Number	Type of Report	Reporter Type
000380677	0	2011-10-03	2011-10-03	MAH	2011089028	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
Adult	Female			Death

Product Information

Product Description	Product Role	Dosage Form	Route	Dosing	Frequency	Therapy Duration
YAZ	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
000471597	0	2012-10-11	2012-10-11	MAH	2012101478	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
40 Years	Female			Death

Product Information

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

Reaction Information

MedDRA Preferred Term	MedDRA Version	Duration
Thrombosis	MedDRA V16.0	