## 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:	-AII-
Route of Administration:	-AII-
Range for Age (years):	-AII-
Patient Gender:	-AII-
Case Serious?	-AII-
Case Outcome:	Death
Report Source:	-AII-
Reporter Type:	-AII-
Domestic or Foreign:	Domestic

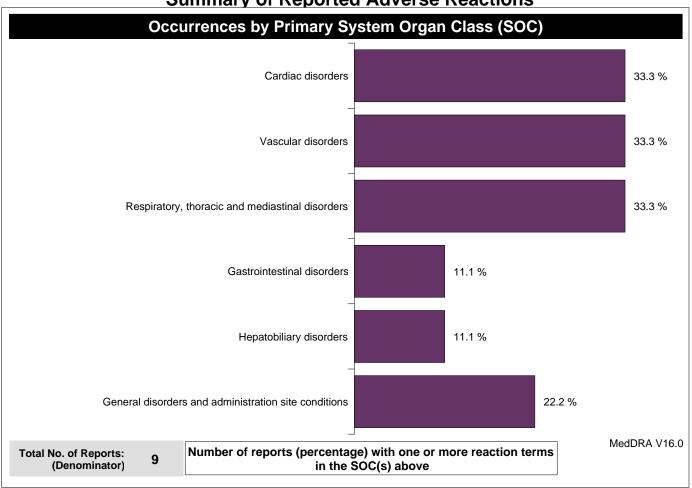
CAVEAT: This summary is based on information from adverse event reports submitted by health professionals and laypersons either directly to Health Canada or via market authorization holders. Each report represents the suspicion, opinion or observation of the individual reporter. The Canada Vigilance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

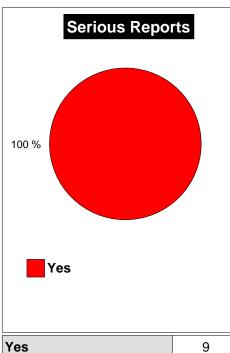


Report Runtime Initial date of receipt: **Total Number of Reports:** 

2013-06-06 - 2:48:12 PM Health Product: RENONE + ETHINYLESTRADIOL) 1965-01-01 to 2013-02-28 9 Reports

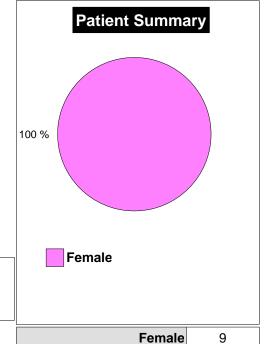
**Canada Vigilance Summary of Reported Adverse Reactions** 





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







Pulmonary embolism

# Canada Vigilance Summary of Reported Adverse Reactions

Report Runtime
Health Product:
Initial date of receipt:

2013-06-06 - 2:48:12 PM RENONE + ETHINYLESTRADIOL) 1965-01-01 to 2013-02-28 9 Reports

Total Number of Reports:

### **Duplicate**

port Informat	ion													
r No	Version No.	Initial Rec. Date	Latest F	Rec. Date	Report Sour	ce	MA	H Number			Type of F	Report		Reporter Type
366016	0	2011-04-07	2011-	-04-07	Community 2011064404		11064404			Spontan	eous		Other Health Professional	
	[	Record	Туре	Liı	nk Aer Number		Seriou	s Report?		Death	: Yes	Disability:		Congenital Anomaly:
	[	Duplic	ate		000366958	]	,	Yes	Life T	hreatening	:	Hospitalization:		Other Medically Imp Condition:
Patient Info	rmation													
Age	Gend	er Heig	ht	Weigh	nt	Repo	rt Outcome							
44 Years	Fema	le					Death		}					
Product Info	rmation													
Pro	duct Descrip	tion	Produc	t Role	Dosa	ige Fori	n		Route		Dosi	ng Freque	ency	Therapy Duration
YAZ			Sus	pect	TABLET			Unknown						
Reaction Inf	ormation													
		М	edDRA Pr	eferred Te	m				N	ledDRA Ver	sion			Duration
Abdominal pair	1									MedDRA V1	16.0			
Asthenia										MedDRA V1	16.0			
Cardiac arrest										MedDRA V1	16.0			

MedDRA V16.0



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Report Runtime Health Product: Initial date of receipt: Total Number of Reports:

2013-06-06 - 2:48:12 PM RENONE + ETHINYLESTRADIOL) 1965-01-01 to 2013-02-28

9 Reports

Report Information
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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:	Yes	Disability:	_	Congenital Anomaly:	
Yes	Life Threatening:	Yes	Hospitalization:	Yes	Other Medically Imp Condition:	

Patient Information	tion			
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	



Cardiovascular disorder

# Canada Vigilance Summary of Reported Adverse Reactions

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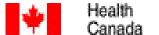
2013-06-06 - 2:48:12 PM RENONE + ETHINYLESTRADIOL) 1965-01-01 to 2013-02-28

9 Reports

### **No Duplicate or Linked Reports**

0	Version No	. Initial Rec. D	te Latest R	c. Date	Report Source	е	MAH N	lumber		Type of I	Report		Reporter Type
46138	1	2010-06-2	2010-0	6-24	MAH		201025	5756NA		Spontar	eous		Physician
		Rec	rd Type	Link	Aer Number		Serious R	eport?	Death:	Yes	Di	sability:	Congenital Anomaly:
		No Duplicate	r Linked Repo	rts		]	Yes	Life	Threatening:		Hospita	lization:	Other Medically Imp Condition:
Patient Inf	formation		٦										
Age		der F	eight	Weight		Report	Outcome						
	Fem	ale				De	eath						
Product In	nformation		7										
Р	Product Descr	iption	Produc	Role	Dosag	ge Form		Route	,	Dosi	ng	Frequency	Therapy Duration
YAZ			Susp	ect T.	ABLET		Or	ral					
			<u> </u>						•				
Reaction II	nformation												
			MedDRA Pre	ferred Term					MedDRA Vers	sion			Duration
Death													
								l	MedDRA V1	6.0	ł		
port Inform	nation		1						MedDRA V1	6.0			
		. Initial Rec. C	ite Latest R	ec. Date	Report Source	e	MAH N	lumber		6.0	Report		Reporter Type
No		o. Initial Rec. E 2010-06-2			Report Source MAH	e		lumber 5999NA					<b>Reporter Type</b> Physician
No	Version No	2010-06-2		7-21		e		5999NA		Type of I	eous	sability:	
No	Version No	2010-06-2	2010-0	7-21 Link	MAH	e	201025	eport?		Type of I Spontar	eous Di	sability:	Physician
No 346426	Version No	2010-06-2	2010-0	7-21 Link	MAH	e	201025 Serious Re	eport?	Death:	Type of I Spontar	eous Di	-	Physician  Congenital Anomaly:
No 346426 Patient Inform	Version No	2010-06-2  Reco	2010-0	7-21 Link	MAH		201025 Serious Re	eport?	Death:	Type of I Spontar	eous Di	-	Physician  Congenital Anomaly:
No 346426 Patient Inf	Version No	2010-06-2  Reco	2010-0 rd Type or Linked Repo	7-21 Link	MAH	Report	201025 Serious Re Yes	eport?	Death:	Type of I Spontar	eous Di	-	Physician  Congenital Anomaly:
No 146426 Patient Inf	Version No	2010-06-2  Reco	2010-0 rd Type or Linked Repo	7-21 Link	MAH	Report	Serious Re Yes	eport?	Death:	Type of I Spontar	eous Di	-	Physician  Congenital Anomaly:
Patient Inf Age  Product In	Version No. 1 formation Gen Fem	2010-06-2  Reco No Duplicate  der Hale	2010-0 rd Type or Linked Repo	7-21 Link	MAH  Aer Number	Report	Serious Re Yes	eport?	Death:	Type of I Spontar	Di Hospita	-	Physician  Congenital Anomaly:
Patient Inf Age  Product In	formation  Gen Fern Formation	2010-06-2  Reco No Duplicate  der Hale	2010-0 rd Type or Linked Repo	7-21 Link rts Weight	MAH  Aer Number	Report O	Serious Re Yes	eport? Lif	Death:	Type of I Spontar Yes	Di Hospita	lization:	Physician  Congenital Anomaly:  Other Medically Imp Condition:
Patient Inf Age  Product In	formation  Gen Fern Formation	2010-06-2  Reco No Duplicate  der Hale	2010-0 rd Type or Linked Repo	7-21 Link rts Weight	MAH  Aer Number  Dosag	Report O	Serious Ro Yes  Outcome eath	eport? Lif	Death:	Type of I Spontar Yes	Di Hospita	lization:	Physician  Congenital Anomaly:  Other Medically Imp Condition:
Patient Inf Age  Product In PYAZ	formation  Gen Fern Formation	2010-06-2  Reco No Duplicate  der Hale	2010-0 rd Type or Linked Repo	7-21 Link rts Weight	MAH  Aer Number  Dosag	Report O	Serious Ro Yes  Outcome eath	eport? Lif	Death:	Type of I Spontar Yes	Di Hospita	lization:	Physician  Congenital Anomaly:  Other Medically Imp Condition:

MedDRA V16.0



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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 Inform	ation			
Age	Gender	Height	Weight	Report Outcome
24 Years	Female	70 Inches	149 Kilograms	Death

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	tion			
Aae	Gender	Heiaht	Weiaht	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	



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 2013-06-06 - 2:48:12 PM

 Health Product:
 RENONE + ETHINYLESTRADIOL)

 date of receipt:
 1965-01-01 to 2013-02-28

9 Reports

### 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	tion				
Age	Gender	Heig	ht	Weight	Report Outcome
16 Years	Female				Death

Product Information	
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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	



Reaction Information

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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	tion			
Age	Gender	Height	Weight	Report Outcome
40 Years	Female			Death

Aye	Gender	neigni	weignt	Report Outcome
40 Years	Female			Death
Product Informa	ation			

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

MedDRA Preferred Term	MedDRA Version	Duration
Thrombosis	MedDRA V16.0	