Clinical trial results:
Cardiovascular outcomes study to evaluate the potential of aleglitazar to reduce cardiovascular risk in patients with a recent acute coronary syndrome (ACS) event and type 2 diabetes mellitus (T2D)

Summary

EudraCT number	2009-012269-71
Trial protocol	DE ES SE DK FR IE HU CZ GB IT
Global end of trial date	18 November 2013

Results information

Result version number	v1 (current)
This version publication date	28 October 2016
First version publication date	28 October 2016

Trial information

Trial identification

Sponsor protocol code	BC22140

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01042769
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	F. Hoffmann-La Roche AG
Sponsor organisation address	Grenzacherstrasse 124, Basel, Switzerland, CH-4070
Public contact	global.trial_information@roche.com, F. Hoffmann-La Roche AG,, +41 61 687 83333, global.trial_information@roche.com
Scientific contact	+41 61 6878333,, Roche Trial Information Hotline,, +41 61 687 83333, global.trial_information@roche.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	17 December 2013
Is this the analysis of the primary completion data?	Yes
Primary completion date	18 November 2013
Global end of trial reached?	Yes
Global end of trial date	18 November 2013
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To determine whether aleglitazar reduces cardiovascular mortality and morbidity (defined as non-fatal myocardial infarction (MI) and non-fatal stroke) in patients with a recent ACS event and T2D.

Protection of trial subjects:

All participants signed an informed consent form before enrollment into the study.

Background therapy:

Contemporary evidence-based medical care for ACS (e.g., antiplatelets, beta-blockers, ACE-inhibitors, and statins), and diabetes (e.g., diet, exercise, antihyperglycemic medications).

Evidence for comparator: -

Actual start date of recruitment	03 May 2010
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	China: 631
Country: Number of subjects enrolled	India: 602
Country: Number of subjects enrolled	Korea, Republic of: 233
Country: Number of subjects enrolled	Thailand: 232
Country: Number of subjects enrolled	Malaysia: 120
Country: Number of subjects enrolled	Australia: 98
Country: Number of subjects enrolled	New Zealand: 61
Country: Number of subjects enrolled	Russian Federation: 42
Country: Number of subjects enrolled	Poland: 638
Country: Number of subjects enrolled	Spain: 448
Country: Number of subjects enrolled	Germany: 279
Country: Number of subjects enrolled	Hungary: 251
Country: Number of subjects enrolled	Italy: 157
Country: Number of subjects enrolled	United Kingdom: 134
Country: Number of subjects enrolled	Sweden: 132
Country: Number of subjects enrolled	Czech Republic: 124
Country: Number of subjects enrolled	Netherlands: 94
Country: Number of subjects enrolled	France: 92
Country: Number of subjects enrolled	Romania: 90
Country: Number of subjects enrolled	Ireland: 43

Country: Number of subjects enrolled	Denmark: 28
Country: Number of subjects enrolled	United States: 1094
Country: Number of subjects enrolled	Canada: 545
Country: Number of subjects enrolled	Mexico: 369
Country: Number of subjects enrolled	Brazil: 533
Country: Number of subjects enrolled	Argentina: 156
Worldwide total number of subjects	7226
EEA total number of subjects	2510

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	4836
From 65 to 84 years	2354
85 years and over	36

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

An Eligibility Screening Form [ESF] documenting the investigator's assessment of each screened patient with regard to the protocol's inclusion and exclusion criteria was completed by the investigator.

Period 1

Period 1 title	Overall study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Data analyst, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Aleglitazar

Arm description:

Aleglitazar 150 µg tablet

Arm type	Experimental
Investigational medicinal product name	Aleglitazar
Investigational medicinal product code	Ro 72-8804/F23
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Once daily

Arm title	Placebo

Arm description:

Placebo

Arm type	Placebo
Investigational medicinal product name	Matching placebo tablet
Investigational medicinal product code	(Ro 72-8804/F20)
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Once daily

Number of subjects in period 1	Aleglitazar	Placebo
Started	3616	3610
Completed	3244	3243
Not completed	372	367
Adverse event, serious fatal	147	139

Consent withdrawn by subject	120	108
Missing information	-	1
Lost to follow-up	105	119

Baseline characteristics

Reporting groups	
Reporting group title	Aleglitazar
Reporting group description: Aleglitazar 150 µg tablet	
Reporting group title	Placebo
Reporting group description: Placebo	

Reporting group values	Aleglitazar	Placebo	Total
Number of subjects	3616	3610	7226
Age categorical Units: Subjects			
Adults (18-64 years)	2374	2462	4836
From 65-84 years	1220	1134	2354
85 years and over	21	14	35
Not recorded	1	0	1
Gender categorical Units: Subjects			
Female	974	991	1965
Male	2641	2619	5260
Not recorded	1	0	1

End points

End points reporting groups	
Reporting group title	Aleglitazar
Reporting group description: Aleglitazar 150 µg tablet	
Reporting group title	Placebo
Reporting group description: Placebo	

Primary: Number of patients with first occurrence of any component of a composite of cardiovascular death, nonfatal myocardial infarction and non-fatal stroke as adjudicated by the Clinical Events Committee (CEC)

End point title	Number of patients with first occurrence of any component of a composite of cardiovascular death, nonfatal myocardial infarction and non-fatal stroke as adjudicated by the Clinical Events Committee (CEC)
End point description:	
End point type	Primary
End point timeframe: 3 years	

End point values	Aleglitazar	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3616	3610		
Units: Patients	344	362		

Statistical analyses

Statistical analysis title	Primary outcome measure
Comparison groups	Placebo v Aleglitazar
Number of subjects included in analysis	7226
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	= 0.566
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.83
upper limit	1.11

Secondary: Number of patients with other cardiovascular outcomes

End point title	Number of patients with other cardiovascular outcomes

End point description:

End point type	Secondary

End point timeframe:

3 years

End point values	Aleglitazar	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3616	3610		
Units: Patients				
Any cardiovscular death	112	98		
Any non-fatal myocardial infarction	212	239		
Any non-fatal stroke	49	52		
All-cause mortality	148	139		
Hosp. for unstable angina	118	156		
Hosp. for heart failure	122	100		

Statistical analyses

No statistical analyses for this end point

Secondary: Mean absolute change from baseline to end of treatment in glycated hemoglobin (HbA1c)

End point title	Mean absolute change from baseline to end of treatment in glycated hemoglobin (HbA1c)

End point description:

End point type	Secondary

End point timeframe:

3 years

End point values	Aleglitazar	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3362	3371		
Units: Value				
arithmetic mean (standard deviation)	-0.7 (± 1.5)	-0.1 (± 1.5)		

Statistical analyses

No statistical analyses for this end point

Secondary: Mean percentage change from baseline to end of treatment in low-density lipoprotein cholesterol (LDL-C)

End point title	Mean percentage change from baseline to end of treatment in low-density lipoprotein cholesterol (LDL-C)

End point description:

End point type	Secondary

End point timeframe:

3 years

End point values	Aleglitazar	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3243	3212		
Units: Value				
arithmetic mean (standard deviation)	23.1 (± 50.8)	16.6 (± 49)		

Statistical analyses

No statistical analyses for this end point

Secondary: Mean percentage change from baseline to end of treatment in high-density lipoprotein cholesterol (HDL-C)

End point title	Mean percentage change from baseline to end of treatment in high-density lipoprotein cholesterol (HDL-C)

End point description:

End point type	Secondary

End point timeframe:

3 years

End point values	Aleglitazar	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3301	3289		
Units: Value				
arithmetic mean (standard deviation)	24.8 (± 27.4)	10.3 (± 23.1)		

Statistical analyses

No statistical analyses for this end point

Secondary: Mean percentage change from baseline to end of treatment in triglycerides (TG)

End point title	Mean percentage change from baseline to end of treatment in triglycerides (TG)

End point description:

End point type	Secondary

End point timeframe:

3 years

End point values	Aleglitazar	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3302	3290		
Units: Value				
arithmetic mean (standard deviation)	-13.1 (± 46.5)	22 (± 67.8)		

Statistical analyses

No statistical analyses for this end point

Secondary: Mean percentage change from baseline to end of treatment in apolipoprotein A-I (ApoA1)

End point title	Mean percentage change from baseline to end of treatment in apolipoprotein A-I (ApoA1)

End point description:

End point type	Secondary

End point timeframe:

3 years

End point values	Aleglitazar	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3296	3279		
Units: Value				
arithmetic mean (standard deviation)	10.3 (± 20.3)	7.9 (± 18.3)		

Statistical analyses

No statistical analyses for this end point

Secondary: Mean percentage change from baseline to end of treatment in apolipoprotein B (ApoB)

End point title	Mean percentage change from baseline to end of treatment in apolipoprotein B (ApoB)

End point description:

End point type	Secondary

End point timeframe:

3 years

End point values	Aleglitazar	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3296	3279		
Units: Value				
arithmetic mean (standard deviation)	4.8 (± 33.2)	10.2 (± 32.8)		

Statistical analyses

No statistical analyses for this end point

Secondary: Mean absolute change from baseline to end of treatment in fibrinogen-C

End point title	Mean absolute change from baseline to end of treatment in fibrinogen-C

End point description:

End point type	Secondary

End point timeframe:

3 years

End point values	Aleglitazar	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3151	3145		
Units: Value				
arithmetic mean (standard deviation)	-110.1 (± 139.5)	-68.2 (± 145.2)		

Statistical analyses

No statistical analyses for this end point

Secondary: Median percent change from baseline to end of treatment (Q1 – Q3) in high-sensitivity C-reactive protein (hs-CRP-C)

End point title	Median percent change from baseline to end of treatment (Q1 – Q3) in high-sensitivity C-reactive protein (hs-CRP-C)

End point description:

End point type	Secondary

End point timeframe:

3 years

End point values	Aleglitazar	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3287	3291		
Units: Value				
median (inter-quartile range (Q1-Q3))	-31.5 (-70.7 to 35)	-23 (-64.9 to 43.7)		

Statistical analyses

No statistical analyses for this end point

Secondary: Mean percentage change from baseline to end of treatment in adiponectin

End point title	Mean percentage change from baseline to end of treatment in adiponectin

End point description:

End point type	Secondary

End point timeframe:

3 years

End point values	Aleglitazar	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3259	3235		
Units: Value				
arithmetic mean (standard deviation)	212 (± 214.2)	16.2 (± 57.4)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of patients with at least one adverse event

End point title	Number of patients with at least one adverse event

End point description:

End point type	Secondary

End point timeframe:

3 years

End point values	Aleglitazar	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3587	3587		
Units: Patients	2719	2515		

Statistical analyses

No statistical analyses for this end point

Secondary: Total number of adverse events

End point title	Total number of adverse events

End point description:

End point type	Secondary

End point timeframe:

3 years

End point values	Aleglitazar	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3587	3587		
Units: AEs	11853	10252		

Statistical analyses

No statistical analyses for this end point

Secondary: Deaths

End point title	Deaths

End point description:

End point type	Secondary

End point timeframe:

3 years

End point values	Aleglitazar	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3587	3587		
Units: Deaths	148	139		

Statistical analyses

No statistical analyses for this end point

Secondary: Patients with at least one serious adverse event

End point title	Patients with at least one serious adverse event

End point description:

End point type	Secondary

End point timeframe:

3 years

End point values	Aleglitazar	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3587	3587		
Units: Patients	901	833		

Statistical analyses

No statistical analyses for this end point

Secondary: Patients with adverse events leading to withdrawal from treatment

End point title	Patients with adverse events leading to withdrawal from treatment

End point description:

End point type	Secondary

End point timeframe:

3 years

End point values	Aleglitazar	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3587	3587		
Units: Patients	286	165		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: Up to 89 weeks.	
Assessment type	Systematic
Dictionary used	
Dictionary name	MedDRA
Dictionary version	16.1
Reporting groups	
Reporting group title	Aleglitazar
Reporting group description: Aleglitazar 150 µg tablet	
Reporting group title	Placebo
Reporting group description: Placebo	

Serious adverse events	Aleglitazar	Placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	1015 / 3587 (28.30%)	947 / 3587 (26.40%)	
number of deaths (all causes)	2	2	
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
PROSTATE CANCER			
subjects affected / exposed	11 / 3587 (0.31%)	13 / 3587 (0.36%)	
occurrences causally related to treatment / all	1 / 11	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
COLON CANCER			
subjects affected / exposed	5 / 3587 (0.14%)	3 / 3587 (0.08%)	
occurrences causally related to treatment / all	1 / 5	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
ADENOCARCINOMA OF COLON			
subjects affected / exposed	4 / 3587 (0.11%)	3 / 3587 (0.08%)	
occurrences causally related to treatment / all	0 / 4	2 / 3	
deaths causally related to treatment / all	0 / 2	0 / 0	
BLADDER CANCER			

subjects affected / exposed	4 / 3587 (0.11%)	3 / 3587 (0.08%)	
occurrences causally related to treatment / all	2 / 4	2 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
BREAST CANCER			
subjects affected / exposed	2 / 3587 (0.06%)	4 / 3587 (0.11%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
LUNG ADENOCARCINOMA			
subjects affected / exposed	3 / 3587 (0.08%)	3 / 3587 (0.08%)	
occurrences causally related to treatment / all	1 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
LUNG NEOPLASM MALIGNANT			
subjects affected / exposed	3 / 3587 (0.08%)	3 / 3587 (0.08%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
BASAL CELL CARCINOMA			
subjects affected / exposed	3 / 3587 (0.08%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
BLADDER TRANSITIONAL CELL CARCINOMA			
subjects affected / exposed	3 / 3587 (0.08%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
PANCREATIC CARCINOMA METASTATIC			
subjects affected / exposed	2 / 3587 (0.06%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 2	0 / 2	
ADENOCARCINOMA GASTRIC			
subjects affected / exposed	1 / 3587 (0.03%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
GASTRIC CANCER			

subjects affected / exposed	2 / 3587 (0.06%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	1 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
METASTASES TO LIVER			
subjects affected / exposed	3 / 3587 (0.08%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
RECTAL CANCER			
subjects affected / exposed	0 / 3587 (0.00%)	3 / 3587 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
RENAL CANCER			
subjects affected / exposed	2 / 3587 (0.06%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
RENAL CELL CARCINOMA			
subjects affected / exposed	3 / 3587 (0.08%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SQUAMOUS CELL CARCINOMA OF LUNG			
subjects affected / exposed	1 / 3587 (0.03%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
B-CELL LYMPHOMA			
subjects affected / exposed	1 / 3587 (0.03%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
BILIARY CANCER METASTATIC			
subjects affected / exposed	2 / 3587 (0.06%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
BREAST CANCER METASTATIC			

subjects affected / exposed	2 / 3587 (0.06%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
NON-SMALL CELL LUNG CANCER			
subjects affected / exposed	0 / 3587 (0.00%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
PANCREATIC CARCINOMA			
subjects affected / exposed	1 / 3587 (0.03%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
UTERINE LEIOMYOMA			
subjects affected / exposed	2 / 3587 (0.06%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ACUTE LEUKAEMIA			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ACUTE MYELOID LEUKAEMIA			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ADENOCARCINOMA			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ADENOCARCINOMA PANCREAS			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ADENOID CYSTIC CARCINOMA			

subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
BENIGN NEOPLASM OF EPIDIDYMIS			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
BENIGN RENAL NEOPLASM			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
BLADDER CANCER RECURRENT			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
BLADDER NEOPLASM			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
BOWEN'S DISEASE			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
BREAST NEOPLASM			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
BRONCHIAL CARCINOMA			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
CARCINOID TUMOUR OF THE DUODENUM			

subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CERVIX CARCINOMA STAGE II			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CHRONIC LYMPHOCYTIC LEUKAEMIA			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CLEAR CELL RENAL CELL CARCINOMA			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CHRONIC MYELOMONOCYTIC LEUKAEMIA			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
COLON CANCER METASTATIC			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
EAR NEOPLASM MALIGNANT			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
EXTRANODAL MARGINAL ZONE B-CELL LYMPHOMA (MALT TYPE)			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ENDOMETRIAL CANCER STAGE II			

subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 1		
GASTROINTESTINAL CARCINOMA				
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 1		
GASTROINTESTINAL NEOPLASM				
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 1	0 / 0		
HEPATIC CANCER METASTATIC				
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)		
occurrences causally related to treatment / all	0 / 0	1 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
GASTROINTESTINAL TRACT ADENOMA				
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
HUERTHLE CELL CARCINOMA				
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
INTESTINAL ADENOCARCINOMA				
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)		
occurrences causally related to treatment / all	0 / 0	1 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
LARYNGEAL SQUAMOUS CELL CARCINOMA				
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
INVASIVE LOBULAR BREAST CARCINOMA				

subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
LENTIGO MALIGNA			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
LIPOMA			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
LUNG ADENOCARCINOMA METASTATIC			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
LUNG CANCER METASTATIC			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
MALIGNANT ASCITES			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
MALIGNANT MELANOMA			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
MALIGNANT PLEURAL EFFUSION			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
MALIGNANT NEOPLASM OF CONJUNCTIVA			

subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
MANTLE CELL LYMPHOMA STAGE IV			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
MEDIASTINUM NEOPLASM			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
MENINGIOMA BENIGN			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
METASTASES TO ADRENALS			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
METASTASES TO BONE			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
METASTASES TO LYMPH NODES			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
METASTASES TO RETROPERITONEUM			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
METASTATIC BRONCHIAL CARCINOMA			

subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
METASTATIC MALIGNANT MELANOMA			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
MYELODYSPLASTIC SYNDROME			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
METASTATIC RENAL CELL CARCINOMA			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
NON-HODGKIN'S LYMPHOMA			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
NEUROMA			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
NON-SMALL CELL LUNG CANCER STAGE I			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
NON-SMALL CELL LUNG CANCER STAGE IIIA			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

OESOPHAGEAL ADENOCARCINOMA			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
OESOPHAGEAL CARCINOMA			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PROSTATE CANCER METASTATIC			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
RECTAL ADENOCARCINOMA			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
RECTOSIGMOID CANCER			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
RENAL NEOPLASM			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
SALIVARY GLAND CANCER			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
SMALL CELL LUNG CANCER			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SQUAMOUS CELL CARCINOMA OF THE TONGUE			

subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
T-CELL LYMPHOMA			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
THYROID ADENOMA			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
URETHRAL CANCER			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
UTERINE CANCER			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
HYPERTENSION			
subjects affected / exposed	10 / 3587 (0.28%)	12 / 3587 (0.33%)	
occurrences causally related to treatment / all	1 / 10	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPERTENSIVE CRISIS			
subjects affected / exposed	8 / 3587 (0.22%)	10 / 3587 (0.28%)	
occurrences causally related to treatment / all	0 / 8	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPOTENSION			
subjects affected / exposed	9 / 3587 (0.25%)	4 / 3587 (0.11%)	
occurrences causally related to treatment / all	0 / 9	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
PERIPHERAL ISCHAEMIA			

subjects affected / exposed	4 / 3587 (0.11%)	8 / 3587 (0.22%)	
occurrences causally related to treatment / all	0 / 6	0 / 8	
deaths causally related to treatment / all	0 / 1	0 / 0	
INTERMITTENT CLAUDICATION			
subjects affected / exposed	3 / 3587 (0.08%)	8 / 3587 (0.22%)	
occurrences causally related to treatment / all	0 / 3	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
PERIPHERAL ARTERIAL OCCLUSIVE DISEASE			
subjects affected / exposed	5 / 3587 (0.14%)	5 / 3587 (0.14%)	
occurrences causally related to treatment / all	0 / 5	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
AORTIC ANEURYSM			
subjects affected / exposed	5 / 3587 (0.14%)	4 / 3587 (0.11%)	
occurrences causally related to treatment / all	0 / 5	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
ACCELERATED HYPERTENSION			
subjects affected / exposed	2 / 3587 (0.06%)	3 / 3587 (0.08%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
DEEP VEIN THROMBOSIS			
subjects affected / exposed	3 / 3587 (0.08%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
EXTREMITY NECROSIS			
subjects affected / exposed	2 / 3587 (0.06%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
ARTERIOSCLEROSIS			
subjects affected / exposed	1 / 3587 (0.03%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 1	
DIABETIC VASCULAR DISORDER			

subjects affected / exposed	0 / 3587 (0.00%)	3 / 3587 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
HAEMATOMA			
subjects affected / exposed	2 / 3587 (0.06%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPOVOLAEMIC SHOCK			
subjects affected / exposed	1 / 3587 (0.03%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
PERIPHERAL VASCULAR DISORDER			
subjects affected / exposed	0 / 3587 (0.00%)	3 / 3587 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPERTENSIVE EMERGENCY			
subjects affected / exposed	0 / 3587 (0.00%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
ILIAC ARTERY OCCLUSION			
subjects affected / exposed	0 / 3587 (0.00%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
MALIGNANT HYPERTENSION			
subjects affected / exposed	0 / 3587 (0.00%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
THROMBOPHLEBITIS			
subjects affected / exposed	1 / 3587 (0.03%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ARTERIAL INSUFFICIENCY			

subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ARTERIAL SPASM			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CIRCULATORY COLLAPSE			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
DIABETIC MICROANGIOPATHY			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
FEMORAL ARTERY ANEURYSM			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
FEMORAL ARTERY EMBOLISM			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
FLUSHING			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ISCHAEMIC LIMB PAIN			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
JUGULAR VEIN THROMBOSIS			

subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
LERICHE SYNDROME			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
LYMPHOEDEMA			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
NECROSIS ISCHAEMIC			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ORTHOSTATIC HYPOTENSION			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PERIPHERAL ARTERY ANEURYSM			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PERIPHERAL ARTERY THROMBOSIS			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
SHOCK HAEMORRHAGIC			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
VARICOSE VEIN			

subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
VASCULAR OCCLUSION			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
VASCULITIS			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
KNEE ARTHROPLASTY			
subjects affected / exposed	1 / 3587 (0.03%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
AORTIC VALVE REPLACEMENT			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CATARACT OPERATION			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CARDIAC PACEMAKER REPLACEMENT			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
FOOT AMPUTATION			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ILEOSTOMY			

subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
IMPLANTABLE DEFIBRILLATOR INSERTION			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
IMPLANTABLE DEFIBRILLATOR REMOVAL			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
LEG AMPUTATION			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PROSTATECTOMY			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
SCAR EXCISION			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
THERAPY CHANGE			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
TOE AMPUTATION			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
TRANSURETHRAL PROSTATECTOMY			

subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
NON-CARDIAC CHEST PAIN			
subjects affected / exposed	93 / 3587 (2.59%)	73 / 3587 (2.04%)	
occurrences causally related to treatment / all	2 / 118	4 / 81	
deaths causally related to treatment / all	0 / 0	0 / 0	
DEATH			
subjects affected / exposed	9 / 3587 (0.25%)	14 / 3587 (0.39%)	
occurrences causally related to treatment / all	0 / 9	1 / 14	
deaths causally related to treatment / all	0 / 9	1 / 14	
SUDDEN DEATH			
subjects affected / exposed	6 / 3587 (0.17%)	10 / 3587 (0.28%)	
occurrences causally related to treatment / all	1 / 6	0 / 10	
deaths causally related to treatment / all	1 / 6	0 / 10	
SUDDEN CARDIAC DEATH			
subjects affected / exposed	9 / 3587 (0.25%)	3 / 3587 (0.08%)	
occurrences causally related to treatment / all	0 / 9	0 / 3	
deaths causally related to treatment / all	0 / 9	0 / 3	
OEDEMA PERIPHERAL			
subjects affected / exposed	6 / 3587 (0.17%)	4 / 3587 (0.11%)	
occurrences causally related to treatment / all	2 / 6	2 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
CHEST DISCOMFORT			
subjects affected / exposed	5 / 3587 (0.14%)	3 / 3587 (0.08%)	
occurrences causally related to treatment / all	1 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
PYREXIA			
subjects affected / exposed	2 / 3587 (0.06%)	4 / 3587 (0.11%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
CHEST PAIN			

subjects affected / exposed	2 / 3587 (0.06%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 2	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
FATIGUE			
subjects affected / exposed	3 / 3587 (0.08%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
IMPAIRED HEALING			
subjects affected / exposed	4 / 3587 (0.11%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 5	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ASTHENIA			
subjects affected / exposed	1 / 3587 (0.03%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
CARDIAC DEATH			
subjects affected / exposed	3 / 3587 (0.08%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 3	0 / 0	
LOCAL SWELLING			
subjects affected / exposed	2 / 3587 (0.06%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
MALAISE			
subjects affected / exposed	1 / 3587 (0.03%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CHILLS			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CYST			

subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
DEVICE BREAKAGE			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
DEVICE DISLOCATION			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
DRUG INTOLERANCE			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ELECTROCUTION			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
GAIT DISTURBANCE			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
GENERAL PHYSICAL HEALTH DETERIORATION			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
GENERALISED OEDEMA			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HERNIA OBSTRUCTIVE			

subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
IMPLANT SITE HAEMORRHAGE			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
INFLAMMATION			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
MEDICAL DEVICE COMPLICATION			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
MEDICAL DEVICE PAIN			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
MULTI-ORGAN FAILURE			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
NECROBIOSIS			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SURGICAL FAILURE			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
ALLERGY TO ARTHROPOD STING			

subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CONTRAST MEDIA ALLERGY			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
DRUG HYPERSENSITIVITY			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
FOOD ALLERGY			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPERSENSITIVITY			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
TRANSPLANT REJECTION			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Social circumstances			
PHYSICAL ASSAULT			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
BENIGN PROSTATIC HYPERPLASIA			
subjects affected / exposed	2 / 3587 (0.06%)	5 / 3587 (0.14%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	

PROSTATITIS			
subjects affected / exposed	1 / 3587 (0.03%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
ERECTILE DYSFUNCTION			
subjects affected / exposed	0 / 3587 (0.00%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
OVARIAN CYST			
subjects affected / exposed	1 / 3587 (0.03%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ACQUIRED HYDROCELE			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
BREAST DYSPLASIA			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
BREAST HAEMATOMA			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ENDOMETRIAL HYPERPLASIA			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
EPIDIDYMITIS			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
GENITAL TRACT INFLAMMATION			

subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
GYNAECOMASTIA			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
MENORRHAGIA			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PROSTATIC OBSTRUCTION			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
VAGINAL HAEMORRHAGE			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
VULVAL ULCERATION			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
DYSPNOEA			
subjects affected / exposed	22 / 3587 (0.61%)	14 / 3587 (0.39%)	
occurrences causally related to treatment / all	2 / 22	0 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
CHRONIC OBSTRUCTIVE PULMONARY DISEASE			
subjects affected / exposed	17 / 3587 (0.47%)	15 / 3587 (0.42%)	
occurrences causally related to treatment / all	0 / 25	0 / 17	
deaths causally related to treatment / all	0 / 1	0 / 0	
PULMONARY OEDEMA			

subjects affected / exposed	9 / 3587 (0.25%)	12 / 3587 (0.33%)	
occurrences causally related to treatment / all	1 / 9	2 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
PLEURAL EFFUSION			
subjects affected / exposed	8 / 3587 (0.22%)	9 / 3587 (0.25%)	
occurrences causally related to treatment / all	0 / 9	1 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
PULMONARY EMBOLISM			
subjects affected / exposed	10 / 3587 (0.28%)	4 / 3587 (0.11%)	
occurrences causally related to treatment / all	0 / 11	0 / 4	
deaths causally related to treatment / all	0 / 2	0 / 0	
RESPIRATORY FAILURE			
subjects affected / exposed	7 / 3587 (0.20%)	7 / 3587 (0.20%)	
occurrences causally related to treatment / all	0 / 7	0 / 7	
deaths causally related to treatment / all	0 / 3	0 / 3	
ACUTE PULMONARY OEDEMA			
subjects affected / exposed	5 / 3587 (0.14%)	8 / 3587 (0.22%)	
occurrences causally related to treatment / all	0 / 7	2 / 8	
deaths causally related to treatment / all	0 / 2	0 / 1	
PNEUMOTHORAX			
subjects affected / exposed	3 / 3587 (0.08%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
DYSPNOEA EXERTIONAL			
subjects affected / exposed	3 / 3587 (0.08%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	1 / 4	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ACUTE RESPIRATORY FAILURE			
subjects affected / exposed	2 / 3587 (0.06%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ASTHMA			

subjects affected / exposed	0 / 3587 (0.00%)	3 / 3587 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
COUGH			
subjects affected / exposed	0 / 3587 (0.00%)	3 / 3587 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
PLEURISY			
subjects affected / exposed	1 / 3587 (0.03%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
PNEUMONIA ASPIRATION			
subjects affected / exposed	2 / 3587 (0.06%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
PNEUMONITIS			
subjects affected / exposed	2 / 3587 (0.06%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PULMONARY HYPERTENSION			
subjects affected / exposed	3 / 3587 (0.08%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
SLEEP APNOEA SYNDROME			
subjects affected / exposed	2 / 3587 (0.06%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
BRONCHITIS CHRONIC			
subjects affected / exposed	2 / 3587 (0.06%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
EPISTAXIS			

subjects affected / exposed	0 / 3587 (0.00%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPOXIA			
subjects affected / exposed	1 / 3587 (0.03%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PLEURITIC PAIN			
subjects affected / exposed	2 / 3587 (0.06%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PULMONARY FIBROSIS			
subjects affected / exposed	1 / 3587 (0.03%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
RESPIRATORY DISTRESS			
subjects affected / exposed	2 / 3587 (0.06%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
ALLERGIC BRONCHITIS			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CHRONIC RESPIRATORY FAILURE			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
DYSPHONIA			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HAEMOPTYSIS			

subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HAEMOTHORAX			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HICCUPS			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYDROPNEUMOTHORAX			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
INTERSTITIAL LUNG DISEASE			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
NASAL POLYPS			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ORTHOPNOEA			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PNEUMOMEDIASTINUM			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PULMONARY THROMBOSIS			

subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
RESPIRATORY ARREST			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Psychiatric disorders			
DEPRESSION			
subjects affected / exposed	4 / 3587 (0.11%)	4 / 3587 (0.11%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
ALCOHOL WITHDRAWAL SYNDROME			
subjects affected / exposed	1 / 3587 (0.03%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
DELIRIUM			
subjects affected / exposed	2 / 3587 (0.06%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SUICIDE ATTEMPT			
subjects affected / exposed	1 / 3587 (0.03%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ALCOHOL ABUSE			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ANXIETY			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
BREATHING-RELATED SLEEP DISORDER			

subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
COMPLETED SUICIDE			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
DELIRIUM TREMENS			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
DRUG DEPENDENCE			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HOMICIDAL IDEATION			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
MENTAL STATUS CHANGES			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PANIC ATTACK			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PSYCHOTIC DISORDER			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SOMATISATION DISORDER			

subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
STRESS			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SUICIDAL IDEATION			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
CHOLECYSTITIS ACUTE			
subjects affected / exposed	9 / 3587 (0.25%)	6 / 3587 (0.17%)	
occurrences causally related to treatment / all	1 / 9	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
CHOLECYSTITIS			
subjects affected / exposed	6 / 3587 (0.17%)	8 / 3587 (0.22%)	
occurrences causally related to treatment / all	0 / 6	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
CHOLELITHIASIS			
subjects affected / exposed	6 / 3587 (0.17%)	7 / 3587 (0.20%)	
occurrences causally related to treatment / all	0 / 6	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
BILE DUCT STONE			
subjects affected / exposed	2 / 3587 (0.06%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CHOLANGITIS			
subjects affected / exposed	1 / 3587 (0.03%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
BILIARY COLIC			

subjects affected / exposed	1 / 3587 (0.03%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
BILE DUCT OBSTRUCTION			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CHOLANGITIS ACUTE			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CHOLECYSTITIS CHRONIC			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CIRRHOSIS ALCOHOLIC			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HAEMOBILIA			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HEPATIC CIRRHOSIS			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HEPATIC FAILURE			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HEPATITIS			

subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HEPATITIS ACUTE			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYDROCHOLECYSTIS			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
JAUNDICE			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
LIVER DISORDER			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
BLOOD CREATININE INCREASED			
subjects affected / exposed	10 / 3587 (0.28%)	4 / 3587 (0.11%)	
occurrences causally related to treatment / all	7 / 10	2 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
INTERNATIONAL NORMALISED RATIO INCREASED			
subjects affected / exposed	4 / 3587 (0.11%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
BLOOD CREATINE PHOSPHOKINASE INCREASED			
subjects affected / exposed	2 / 3587 (0.06%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	2 / 2	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
BLOOD PRESSURE INCREASED			

subjects affected / exposed	2 / 3587 (0.06%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
EJECTION FRACTION DECREASED			
subjects affected / exposed	2 / 3587 (0.06%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
TROPONIN INCREASED			
subjects affected / exposed	3 / 3587 (0.08%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
BLOOD GLUCOSE INCREASED			
subjects affected / exposed	1 / 3587 (0.03%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
WEIGHT DECREASED			
subjects affected / exposed	2 / 3587 (0.06%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
TRANSAMINASES INCREASED			
subjects affected / exposed	2 / 3587 (0.06%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
WEIGHT INCREASED			
subjects affected / exposed	2 / 3587 (0.06%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
TROPONIN I INCREASED			
subjects affected / exposed	1 / 3587 (0.03%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ALANINE AMINOTRANSFERASE INCREASED			

subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
BLOOD BILIRUBIN INCREASED			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
BLOOD POTASSIUM DECREASED			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
BLOOD PRESSURE DECREASED			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
BODY TEMPERATURE INCREASED			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
BLOOD URINE PRESENT			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CARDIAC ENZYMES INCREASED			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ELECTROCARDIOGRAM T WAVE INVERSION			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
EXERCISE TEST ABNORMAL			

subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
GAMMA-GLUTAMYLTRANSFERASE INCREASED				
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)		
occurrences causally related to treatment / all	0 / 0	1 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
GENERAL PHYSICAL CONDITION ABNORMAL				
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
GLOMERULAR FILTRATION RATE DECREASED				
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
HAEMATOCRIT DECREASED				
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
HAEMOGLOBIN DECREASED				
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
HEPATIC ENZYME INCREASED				
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)		
occurrences causally related to treatment / all	0 / 0	1 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
N-TERMINAL PROHORMONE BRAIN NATRIURETIC PEPTIDE INCREASED				
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		

Injury, poisoning and procedural complications			
FEMUR FRACTURE			
subjects affected / exposed	7 / 3587 (0.20%)	4 / 3587 (0.11%)	
occurrences causally related to treatment / all	1 / 7	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
FALL			
subjects affected / exposed	7 / 3587 (0.20%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 7	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
HIP FRACTURE			
subjects affected / exposed	3 / 3587 (0.08%)	4 / 3587 (0.11%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
ANKLE FRACTURE			
subjects affected / exposed	4 / 3587 (0.11%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	1 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HUMERUS FRACTURE			
subjects affected / exposed	3 / 3587 (0.08%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
SUBDURAL HAEMATOMA			
subjects affected / exposed	5 / 3587 (0.14%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 5	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
FOOT FRACTURE			
subjects affected / exposed	3 / 3587 (0.08%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
POST PROCEDURAL HAEMORRHAGE			
subjects affected / exposed	0 / 3587 (0.00%)	4 / 3587 (0.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	

LACERATION			
subjects affected / exposed	2 / 3587 (0.06%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
VASCULAR PSEUDOANEURYSM			
subjects affected / exposed	0 / 3587 (0.00%)	4 / 3587 (0.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
CONCUSSION			
subjects affected / exposed	1 / 3587 (0.03%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
CORONARY ARTERY RESTENOSIS			
subjects affected / exposed	1 / 3587 (0.03%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
INCISIONAL HERNIA			
subjects affected / exposed	0 / 3587 (0.00%)	3 / 3587 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
MENISCUS INJURY			
subjects affected / exposed	1 / 3587 (0.03%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
POST PROCEDURAL HAEMATOMA			
subjects affected / exposed	1 / 3587 (0.03%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
SPINAL COMPRESSION FRACTURE			
subjects affected / exposed	2 / 3587 (0.06%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
THORACIC VERTEBRAL FRACTURE			

subjects affected / exposed	2 / 3587 (0.06%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
TOXICITY TO VARIOUS AGENTS			
subjects affected / exposed	2 / 3587 (0.06%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CHEST INJURY			
subjects affected / exposed	1 / 3587 (0.03%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CRANIOCEREBRAL INJURY			
subjects affected / exposed	0 / 3587 (0.00%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
COMMINUTED FRACTURE			
subjects affected / exposed	0 / 3587 (0.00%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
FACIAL BONES FRACTURE			
subjects affected / exposed	1 / 3587 (0.03%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
FEMORAL NECK FRACTURE			
subjects affected / exposed	1 / 3587 (0.03%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
JOINT INJURY			
subjects affected / exposed	0 / 3587 (0.00%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
LIMB INJURY			

subjects affected / exposed	0 / 3587 (0.00%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
LOWER LIMB FRACTURE			
subjects affected / exposed	0 / 3587 (0.00%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
PATELLA FRACTURE			
subjects affected / exposed	1 / 3587 (0.03%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
PUBIS FRACTURE			
subjects affected / exposed	2 / 3587 (0.06%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ROAD TRAFFIC ACCIDENT			
subjects affected / exposed	0 / 3587 (0.00%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
RADIUS FRACTURE			
subjects affected / exposed	2 / 3587 (0.06%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SUBDURAL HAEMORRHAGE			
subjects affected / exposed	1 / 3587 (0.03%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
TENDON RUPTURE			
subjects affected / exposed	1 / 3587 (0.03%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
THERMAL BURN			

subjects affected / exposed	1 / 3587 (0.03%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
TIBIA FRACTURE			
subjects affected / exposed	0 / 3587 (0.00%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
ACCIDENT			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
ACCIDENTAL OVERDOSE			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ACETABULUM FRACTURE			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ALCOHOL POISONING			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
AVULSION FRACTURE			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
BONE FISSURE			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
FIBULA FRACTURE			

subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
GASTROINTESTINAL INJURY			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HAND FRACTURE			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
IMPACTED FRACTURE			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HEAD INJURY			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
JOINT DISLOCATION			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
LIGAMENT SPRAIN			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
LIMB TRAUMATIC AMPUTATION			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
LUMBAR VERTEBRAL FRACTURE			

subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
MECHANICAL VENTILATION COMPLICATION			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
MULTIPLE INJURIES			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
OVERDOSE			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PELVIC FRACTURE			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PERIPROSTHETIC FRACTURE			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
POST PROCEDURAL SWELLING			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
POSTOPERATIVE RESPIRATORY FAILURE			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
POSTPERICARDIOTOMY SYNDROME			

subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
PULMONARY CONTUSION				
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
RESPIRATORY FUME INHALATION DISORDER				
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
RIB FRACTURE				
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
SPINAL FRACTURE				
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
STERNAL FRACTURE				
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
UPPER LIMB FRACTURE				
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
VACCINATION COMPLICATION				
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
VASCULAR GRAFT OCCLUSION				

subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
VASCULAR GRAFT THROMBOSIS			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
VITH NERVE INJURY			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
WOUND DEHISCENCE			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
WOUND SECRETION			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
WRIST FRACTURE			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital, familial and genetic disorders			
ATRIAL SEPTAL DEFECT			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYDROCELE			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPERTROPHIC CARDIOMYOPATHY			

subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PHIMOSIS			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PYLORIC STENOSIS			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SYRINGOMYELIA			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
ANGINA PECTORIS			
subjects affected / exposed	86 / 3587 (2.40%)	87 / 3587 (2.43%)	
occurrences causally related to treatment / all	5 / 96	1 / 100	
deaths causally related to treatment / all	0 / 0	0 / 0	
CARDIAC FAILURE			
subjects affected / exposed	109 / 3587 (3.04%)	62 / 3587 (1.73%)	
occurrences causally related to treatment / all	21 / 147	12 / 93	
deaths causally related to treatment / all	1 / 11	0 / 8	
CARDIAC FAILURE CONGESTIVE			
subjects affected / exposed	63 / 3587 (1.76%)	64 / 3587 (1.78%)	
occurrences causally related to treatment / all	14 / 82	12 / 88	
deaths causally related to treatment / all	0 / 0	0 / 2	
ATRIAL FIBRILLATION			
subjects affected / exposed	29 / 3587 (0.81%)	20 / 3587 (0.56%)	
occurrences causally related to treatment / all	1 / 40	0 / 23	
deaths causally related to treatment / all	0 / 0	0 / 0	
CARDIAC ARREST			

subjects affected / exposed	13 / 3587 (0.36%)	13 / 3587 (0.36%)	
occurrences causally related to treatment / all	0 / 13	1 / 13	
deaths causally related to treatment / all	0 / 11	1 / 10	
CORONARY ARTERY DISEASE			
subjects affected / exposed	11 / 3587 (0.31%)	12 / 3587 (0.33%)	
occurrences causally related to treatment / all	0 / 13	0 / 13	
deaths causally related to treatment / all	0 / 2	0 / 3	
CARDIAC FAILURE ACUTE			
subjects affected / exposed	11 / 3587 (0.31%)	11 / 3587 (0.31%)	
occurrences causally related to treatment / all	0 / 14	1 / 12	
deaths causally related to treatment / all	0 / 1	0 / 0	
ARRHYTHMIA			
subjects affected / exposed	8 / 3587 (0.22%)	9 / 3587 (0.25%)	
occurrences causally related to treatment / all	1 / 8	1 / 9	
deaths causally related to treatment / all	0 / 1	0 / 2	
VENTRICULAR TACHYCARDIA			
subjects affected / exposed	6 / 3587 (0.17%)	8 / 3587 (0.22%)	
occurrences causally related to treatment / all	0 / 6	2 / 9	
deaths causally related to treatment / all	0 / 0	0 / 1	
MYOCARDIAL ISCHAEMIA			
subjects affected / exposed	7 / 3587 (0.20%)	4 / 3587 (0.11%)	
occurrences causally related to treatment / all	0 / 7	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 0	
ACUTE LEFT VENTRICULAR FAILURE			
subjects affected / exposed	5 / 3587 (0.14%)	5 / 3587 (0.14%)	
occurrences causally related to treatment / all	5 / 5	1 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
CARDIOGENIC SHOCK			
subjects affected / exposed	7 / 3587 (0.20%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 7	1 / 2	
deaths causally related to treatment / all	5 / 5	1 / 1	
LEFT VENTRICULAR FAILURE			

subjects affected / exposed	2 / 3587 (0.06%)	7 / 3587 (0.20%)	
occurrences causally related to treatment / all	0 / 2	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 3	
AORTIC VALVE STENOSIS			
subjects affected / exposed	5 / 3587 (0.14%)	3 / 3587 (0.08%)	
occurrences causally related to treatment / all	1 / 7	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
ATRIAL FLUTTER			
subjects affected / exposed	3 / 3587 (0.08%)	5 / 3587 (0.14%)	
occurrences causally related to treatment / all	1 / 3	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
LEFT VENTRICULAR DYSFUNCTION			
subjects affected / exposed	2 / 3587 (0.06%)	6 / 3587 (0.17%)	
occurrences causally related to treatment / all	0 / 2	1 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
VENTRICULAR FIBRILLATION			
subjects affected / exposed	3 / 3587 (0.08%)	3 / 3587 (0.08%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 0	
BRADYCARDIA			
subjects affected / exposed	2 / 3587 (0.06%)	5 / 3587 (0.14%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
CARDIO-RESPIRATORY ARREST			
subjects affected / exposed	3 / 3587 (0.08%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 2	0 / 2	
ISCHAEMIC CARDIOMYOPATHY			
subjects affected / exposed	3 / 3587 (0.08%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
SICK SINUS SYNDROME			

subjects affected / exposed	1 / 3587 (0.03%)	4 / 3587 (0.11%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
ATRIOVENTRICULAR BLOCK COMPLETE			
subjects affected / exposed	2 / 3587 (0.06%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
CARDIAC DISCOMFORT			
subjects affected / exposed	1 / 3587 (0.03%)	3 / 3587 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
CARDIAC FAILURE CHRONIC			
subjects affected / exposed	3 / 3587 (0.08%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PALPITATIONS			
subjects affected / exposed	1 / 3587 (0.03%)	3 / 3587 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
CORONARY ARTERY STENOSIS			
subjects affected / exposed	2 / 3587 (0.06%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
PERICARDITIS			
subjects affected / exposed	3 / 3587 (0.08%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ATRIOVENTRICULAR BLOCK			
subjects affected / exposed	2 / 3587 (0.06%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PERICARDIAL EFFUSION			

subjects affected / exposed	1 / 3587 (0.03%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
SUPRAVENTRICULAR TACHYCARDIA			
subjects affected / exposed	1 / 3587 (0.03%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
TACHYCARDIA			
subjects affected / exposed	0 / 3587 (0.00%)	3 / 3587 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
VENTRICULAR EXTRASYSTOLES			
subjects affected / exposed	2 / 3587 (0.06%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ATRIAL TACHYCARDIA			
subjects affected / exposed	1 / 3587 (0.03%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ATRIOVENTRICULAR BLOCK SECOND DEGREE			
subjects affected / exposed	2 / 3587 (0.06%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CARDIAC ASTHMA			
subjects affected / exposed	0 / 3587 (0.00%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
EXTRASYSTOLES			
subjects affected / exposed	1 / 3587 (0.03%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
MITRAL VALVE INCOMPETENCE			

subjects affected / exposed	1 / 3587 (0.03%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
RIGHT VENTRICULAR FAILURE			
subjects affected / exposed	2 / 3587 (0.06%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ARTERIOSPASM CORONARY			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CARDIAC AMYLOIDOSIS			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
CARDIAC TAMPONADE			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CARDIOMYOPATHY ACUTE			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CARDIOPULMONARY FAILURE			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
CARDIOVASCULAR DISORDER			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
CARDIOVASCULAR INSUFFICIENCY			

subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CHRONIC LEFT VENTRICULAR FAILURE			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CHRONOTROPIC INCOMPETENCE			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CORONARY ARTERY THROMBOSIS			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
DRESSLER'S SYNDROME			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
INTRACARDIAC THROMBUS			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
LOW CARDIAC OUTPUT SYNDROME			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
PRINZMETAL ANGINA			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
RESTRICTIVE CARDIOMYOPATHY			

subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SINUS ARRHYTHMIA			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SINUS TACHYCARDIA			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
STRESS CARDIOMYOPATHY			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
VENTRICULAR ARRHYTHMIA			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
VENTRICULAR FAILURE			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
SYNCOPE			
subjects affected / exposed	22 / 3587 (0.61%)	23 / 3587 (0.64%)	
occurrences causally related to treatment / all	0 / 23	1 / 23	
deaths causally related to treatment / all	0 / 0	0 / 0	
TRANSIENT ISCHAEMIC ATTACK			
subjects affected / exposed	10 / 3587 (0.28%)	9 / 3587 (0.25%)	
occurrences causally related to treatment / all	2 / 10	2 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
CAROTID ARTERY STENOSIS			

subjects affected / exposed	4 / 3587 (0.11%)	4 / 3587 (0.11%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
DIZZINESS			
subjects affected / exposed	2 / 3587 (0.06%)	5 / 3587 (0.14%)	
occurrences causally related to treatment / all	0 / 2	1 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
HEADACHE			
subjects affected / exposed	2 / 3587 (0.06%)	3 / 3587 (0.08%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
DIABETIC NEUROPATHY			
subjects affected / exposed	4 / 3587 (0.11%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PRESYNCOPE			
subjects affected / exposed	3 / 3587 (0.08%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
VERTEBROBASILAR INSUFFICIENCY			
subjects affected / exposed	2 / 3587 (0.06%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	1 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
CARPAL TUNNEL SYNDROME			
subjects affected / exposed	2 / 3587 (0.06%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CONVULSION			
subjects affected / exposed	1 / 3587 (0.03%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 1	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
EPILEPSY			

subjects affected / exposed	3 / 3587 (0.08%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPERTENSIVE ENCEPHALOPATHY			
subjects affected / exposed	1 / 3587 (0.03%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
PARAESTHESIA			
subjects affected / exposed	1 / 3587 (0.03%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
VIITH NERVE PARALYSIS			
subjects affected / exposed	3 / 3587 (0.08%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CAROTID ARTERIOSCLEROSIS			
subjects affected / exposed	1 / 3587 (0.03%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
COMA			
subjects affected / exposed	0 / 3587 (0.00%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
DEMENTIA			
subjects affected / exposed	0 / 3587 (0.00%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
HEMIPARESIS			
subjects affected / exposed	0 / 3587 (0.00%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
MIGRAINE			

subjects affected / exposed	1 / 3587 (0.03%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
SCIATICA			
subjects affected / exposed	1 / 3587 (0.03%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
SUBARACHNOID HAEMORRHAGE			
subjects affected / exposed	1 / 3587 (0.03%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
ALCOHOLIC SEIZURE			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ATAXIA			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CAROTID ARTERY ANEURYSM			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CAROTID ARTERY DISEASE			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CEREBRAL HAEMORRHAGE			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CEREBRAL ISCHAEMIA			

subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CEREBROVASCULAR INSUFFICIENCY			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CERVICAL RADICULOPATHY			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CERVICOBRACHIAL SYNDROME			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
COGNITIVE DISORDER			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ENCEPHALITIS			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ENCEPHALOPATHY			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HEMIPLEGIC MIGRAINE			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
GRAND MAL CONVULSION			

subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPOGLYCAEMIC COMA			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPOGLYCAEMIC SEIZURE			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPOGLYCAEMIC UNCONSCIOUSNESS			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPONATRAEMIC ENCEPHALOPATHY			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
LOSS OF CONSCIOUSNESS			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
LUMBAR RADICULOPATHY			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
MEMORY IMPAIRMENT			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
MENINGITIS NONINFECTIVE			

subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
METABOLIC ENCEPHALOPATHY			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
MONOPARESIS			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
NERVE COMPRESSION			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
NEURALGIA			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
NORMAL PRESSURE HYDROCEPHALUS			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
POLYNEUROPATHY			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
SPEECH DISORDER			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
STATUS EPILEPTICUS			

subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
VITH NERVE PARALYSIS			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
VOCAL CORD PARALYSIS			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	21 / 3587 (0.59%)	18 / 3587 (0.50%)	
occurrences causally related to treatment / all	0 / 27	0 / 21	
deaths causally related to treatment / all	0 / 0	0 / 0	
IRON DEFICIENCY ANAEMIA			
subjects affected / exposed	5 / 3587 (0.14%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
MICROCYTIC ANAEMIA			
subjects affected / exposed	0 / 3587 (0.00%)	3 / 3587 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
COAGULOPATHY			
subjects affected / exposed	2 / 3587 (0.06%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
FEBRILE NEUTROPENIA			
subjects affected / exposed	1 / 3587 (0.03%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
PERNICIOUS ANAEMIA			

subjects affected / exposed	2 / 3587 (0.06%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HAEMORRHAGIC ANAEMIA			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
NORMOCHROMIC NORMOCYTIC ANAEMIA			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PANCYTOPENIA			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
SPLENIC INFARCTION			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
THROMBOCYTOPENIA			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
VERTIGO			
subjects affected / exposed	5 / 3587 (0.14%)	3 / 3587 (0.08%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
VERTIGO POSITIONAL			
subjects affected / exposed	1 / 3587 (0.03%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
MIXED DEAFNESS			

subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
VESTIBULAR DISORDER			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
CATARACT			
subjects affected / exposed	9 / 3587 (0.25%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 9	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
RETINAL ARTERY OCCLUSION			
subjects affected / exposed	2 / 3587 (0.06%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
VITREOUS HAEMORRHAGE			
subjects affected / exposed	1 / 3587 (0.03%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
AMAUROSIS			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CONJUNCTIVAL HAEMORRHAGE			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
DIABETIC RETINOPATHY			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
GLAUCOMA			

subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
LENTICULAR OPACITIES			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
VISUAL ACUITY REDUCED			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
VISUAL IMPAIRMENT			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
UPPER GASTROINTESTINAL HAEMORRHAGE			
subjects affected / exposed	22 / 3587 (0.61%)	13 / 3587 (0.36%)	
occurrences causally related to treatment / all	3 / 23	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
GASTRIC ULCER HAEMORRHAGE			
subjects affected / exposed	7 / 3587 (0.20%)	4 / 3587 (0.11%)	
occurrences causally related to treatment / all	0 / 7	1 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
LOWER GASTROINTESTINAL HAEMORRHAGE			
subjects affected / exposed	10 / 3587 (0.28%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 10	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ABDOMINAL PAIN			
subjects affected / exposed	6 / 3587 (0.17%)	4 / 3587 (0.11%)	
occurrences causally related to treatment / all	0 / 9	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
DUODENAL ULCER HAEMORRHAGE			

subjects affected / exposed	6 / 3587 (0.17%)	4 / 3587 (0.11%)	
occurrences causally related to treatment / all	0 / 6	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
ABDOMINAL PAIN UPPER			
subjects affected / exposed	4 / 3587 (0.11%)	5 / 3587 (0.14%)	
occurrences causally related to treatment / all	1 / 4	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
PANCREATITIS ACUTE			
subjects affected / exposed	3 / 3587 (0.08%)	6 / 3587 (0.17%)	
occurrences causally related to treatment / all	1 / 3	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 1	
GASTROOESOPHAGEAL REFLUX DISEASE			
subjects affected / exposed	5 / 3587 (0.14%)	3 / 3587 (0.08%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
INGUINAL HERNIA			
subjects affected / exposed	2 / 3587 (0.06%)	6 / 3587 (0.17%)	
occurrences causally related to treatment / all	1 / 2	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
GASTRITIS			
subjects affected / exposed	3 / 3587 (0.08%)	4 / 3587 (0.11%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
DYSPEPSIA			
subjects affected / exposed	4 / 3587 (0.11%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
GASTROINTESTINAL HAEMORRHAGE			
subjects affected / exposed	2 / 3587 (0.06%)	4 / 3587 (0.11%)	
occurrences causally related to treatment / all	0 / 2	1 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
LARGE INTESTINE POLYP			

subjects affected / exposed	5 / 3587 (0.14%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 5	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PANCREATITIS			
subjects affected / exposed	2 / 3587 (0.06%)	4 / 3587 (0.11%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
GASTRIC ULCER			
subjects affected / exposed	3 / 3587 (0.08%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
HAEMORRHOIDS			
subjects affected / exposed	4 / 3587 (0.11%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
MELAENA			
subjects affected / exposed	4 / 3587 (0.11%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
RECTAL HAEMORRHAGE			
subjects affected / exposed	4 / 3587 (0.11%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	1 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
VOMITING			
subjects affected / exposed	0 / 3587 (0.00%)	5 / 3587 (0.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 1	
CONSTIPATION			
subjects affected / exposed	1 / 3587 (0.03%)	3 / 3587 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
DIARRHOEA			

subjects affected / exposed	1 / 3587 (0.03%)	3 / 3587 (0.08%)	
occurrences causally related to treatment / all	0 / 1	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
DIVERTICULUM			
subjects affected / exposed	1 / 3587 (0.03%)	3 / 3587 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
DYSPHAGIA			
subjects affected / exposed	2 / 3587 (0.06%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
NAUSEA			
subjects affected / exposed	2 / 3587 (0.06%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
GASTRITIS EROSIVE			
subjects affected / exposed	2 / 3587 (0.06%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	1 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HIATUS HERNIA			
subjects affected / exposed	2 / 3587 (0.06%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
SMALL INTESTINAL OBSTRUCTION			
subjects affected / exposed	1 / 3587 (0.03%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
ABDOMINAL HERNIA			
subjects affected / exposed	1 / 3587 (0.03%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ANAL HAEMORRHAGE			

subjects affected / exposed	2 / 3587 (0.06%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
COLITIS			
subjects affected / exposed	0 / 3587 (0.00%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
DIVERTICULITIS INTESTINAL HAEMORRHAGIC			
subjects affected / exposed	1 / 3587 (0.03%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
DIVERTICULUM INTESTINAL HAEMORRHAGIC			
subjects affected / exposed	1 / 3587 (0.03%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ENTERITIS			
subjects affected / exposed	1 / 3587 (0.03%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ENTEROCOLITIS			
subjects affected / exposed	0 / 3587 (0.00%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
GASTROINTESTINAL ANGIODYSPLASIA HAEMORRHAGIC			
subjects affected / exposed	0 / 3587 (0.00%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
IMPAIRED GASTRIC EMPTYING			
subjects affected / exposed	0 / 3587 (0.00%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
INGUINAL HERNIA, OBSTRUCTIVE			

subjects affected / exposed	1 / 3587 (0.03%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
INTESTINAL OBSTRUCTION			
subjects affected / exposed	1 / 3587 (0.03%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
INTESTINAL PERFORATION			
subjects affected / exposed	1 / 3587 (0.03%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
PEPTIC ULCER HAEMORRHAGE			
subjects affected / exposed	2 / 3587 (0.06%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ABDOMINAL ADHESIONS			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ABDOMINAL DISCOMFORT			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ABDOMINAL PAIN LOWER			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ABDOMINAL WALL HAEMATOMA			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CHANGE OF BOWEL HABIT			

subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
COLITIS ISCHAEMIC			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
COLITIS ULCERATIVE			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
DIVERTICULAR PERFORATION			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
DIVERTICULUM INTESTINAL			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
DUODENAL STENOSIS			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
DUODENITIS			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
EPIGASTRIC DISCOMFORT			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
FOOD POISONING			

subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
GASTRIC ANTRAL VASCULAR ECTASIA			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
GASTRODUODENAL ULCER			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
GASTRODUODENITIS HAEMORRHAGIC			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
GASTROINTESTINAL DISORDER			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
GASTROINTESTINAL NECROSIS			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
GASTROINTESTINAL ULCER HAEMORRHAGE			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
GINGIVAL BLEEDING			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HAEMATEMESIS			

subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HAEMORRHAGIC EROSIVE GASTRITIS			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ILEUS			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
INGUINAL HERNIA STRANGULATED			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
INTESTINAL ISCHAEMIA			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
LARGE INTESTINAL ULCER HAEMORRHAGE			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
LARGE INTESTINE PERFORATION			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
OESOPHAGITIS			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PANCREATITIS NECROTISING			

subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PEPTIC ULCER			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PERITONEAL HAEMORRHAGE			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PNEUMOPERITONEUM			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PROCTALGIA			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
RETROPERITONEAL HAEMATOMA			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SIGMOIDITIS			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SMALL INTESTINAL HAEMORRHAGE			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SMALL INTESTINAL ULCER HAEMORRHAGE			

subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
SUBILEUS			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
UMBILICAL HERNIA, OBSTRUCTIVE			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
SKIN ULCER			
subjects affected / exposed	3 / 3587 (0.08%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
DIABETIC FOOT			
subjects affected / exposed	0 / 3587 (0.00%)	3 / 3587 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
DECUBITUS ULCER			
subjects affected / exposed	1 / 3587 (0.03%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PSORIASIS			
subjects affected / exposed	1 / 3587 (0.03%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
DERMATITIS ALLERGIC			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ECCHYMOSIS			

subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PEMPHIGUS			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
RASH GENERALISED			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
SKIN FISSURES			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
RENAL FAILURE ACUTE			
subjects affected / exposed	33 / 3587 (0.92%)	22 / 3587 (0.61%)	
occurrences causally related to treatment / all	12 / 35	4 / 23	
deaths causally related to treatment / all	0 / 0	0 / 3	
RENAL FAILURE			
subjects affected / exposed	14 / 3587 (0.39%)	12 / 3587 (0.33%)	
occurrences causally related to treatment / all	0 / 14	2 / 12	
deaths causally related to treatment / all	0 / 1	0 / 2	
RENAL IMPAIRMENT			
subjects affected / exposed	6 / 3587 (0.17%)	6 / 3587 (0.17%)	
occurrences causally related to treatment / all	3 / 6	1 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
HAEMATURIA			
subjects affected / exposed	5 / 3587 (0.14%)	4 / 3587 (0.11%)	
occurrences causally related to treatment / all	1 / 5	1 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
NEPHROLITHIASIS			

subjects affected / exposed	6 / 3587 (0.17%)	3 / 3587 (0.08%)	
occurrences causally related to treatment / all	1 / 7	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
RENAL FAILURE CHRONIC			
subjects affected / exposed	5 / 3587 (0.14%)	4 / 3587 (0.11%)	
occurrences causally related to treatment / all	0 / 5	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
URINARY RETENTION			
subjects affected / exposed	5 / 3587 (0.14%)	4 / 3587 (0.11%)	
occurrences causally related to treatment / all	0 / 5	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
RENAL COLIC			
subjects affected / exposed	3 / 3587 (0.08%)	5 / 3587 (0.14%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
CALCULUS URETERIC			
subjects affected / exposed	1 / 3587 (0.03%)	3 / 3587 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
CALCULUS URINARY			
subjects affected / exposed	1 / 3587 (0.03%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYDRONEPHROSIS			
subjects affected / exposed	0 / 3587 (0.00%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
PRERENAL FAILURE			
subjects affected / exposed	0 / 3587 (0.00%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
RENAL ARTERY STENOSIS			

subjects affected / exposed	0 / 3587 (0.00%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
URETHRAL STENOSIS			
subjects affected / exposed	1 / 3587 (0.03%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
AZOTAEMIA			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
BLADDER TAMPONADE			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CYSTITIS HAEMORRHAGIC			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
DIABETIC NEPHROPATHY			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
NEPHRITIS			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
RENAL CYST			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
URINARY TRACT OBSTRUCTION			

subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
URINOMA			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
HYPERTHYROIDISM			
subjects affected / exposed	2 / 3587 (0.06%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
ADRENOCORTICAL INSUFFICIENCY ACUTE			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
No Coding available			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
OSTEOARTHRITIS			
subjects affected / exposed	14 / 3587 (0.39%)	8 / 3587 (0.22%)	
occurrences causally related to treatment / all	0 / 14	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
MUSCULOSKELETAL CHEST PAIN			
subjects affected / exposed	6 / 3587 (0.17%)	9 / 3587 (0.25%)	
occurrences causally related to treatment / all	0 / 6	2 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
BACK PAIN			
subjects affected / exposed	2 / 3587 (0.06%)	5 / 3587 (0.14%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	

INTERVERTEBRAL DISC PROTRUSION			
subjects affected / exposed	7 / 3587 (0.20%)	4 / 3587 (0.11%)	
occurrences causally related to treatment / all	0 / 7	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
MUSCULOSKELETAL PAIN			
subjects affected / exposed	2 / 3587 (0.06%)	3 / 3587 (0.08%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
MYALGIA			
subjects affected / exposed	2 / 3587 (0.06%)	3 / 3587 (0.08%)	
occurrences causally related to treatment / all	1 / 2	1 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
ARTHRITIS			
subjects affected / exposed	3 / 3587 (0.08%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
RHEUMATOID ARTHRITIS			
subjects affected / exposed	2 / 3587 (0.06%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
SPINAL OSTEOARTHRITIS			
subjects affected / exposed	0 / 3587 (0.00%)	4 / 3587 (0.11%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
ARTHRALGIA			
subjects affected / exposed	1 / 3587 (0.03%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
RHABDOMYOLYSIS			
subjects affected / exposed	2 / 3587 (0.06%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	1 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
LUMBAR SPINAL STENOSIS			

subjects affected / exposed	2 / 3587 (0.06%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
SPINAL COLUMN STENOSIS			
subjects affected / exposed	1 / 3587 (0.03%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
MUSCULAR WEAKNESS			
subjects affected / exposed	2 / 3587 (0.06%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
TENDONITIS			
subjects affected / exposed	0 / 3587 (0.00%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
PAIN IN EXTREMITY			
subjects affected / exposed	1 / 3587 (0.03%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ARTHRITIS REACTIVE			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
EXOSTOSIS			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
INTERVERTEBRAL DISC DEGENERATION			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
INTERVERTEBRAL DISC DISORDER			

subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
MUSCLE HAEMORRHAGE			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
MUSCLE SPASMS			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
MYOPATHY			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
OSTEOCHONDROSIS			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PALINDROMIC RHEUMATISM			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ROTATOR CUFF SYNDROME			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SCLERODERMA			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
SPINAL DISORDER			

subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
SPINAL PAIN			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
SPONDYLITIS			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SYSTEMIC LUPUS ERYTHEMATOSUS			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
PNEUMONIA			
subjects affected / exposed	43 / 3587 (1.20%)	40 / 3587 (1.12%)	
occurrences causally related to treatment / all	0 / 47	0 / 45	
deaths causally related to treatment / all	0 / 3	0 / 3	
CELLULITIS			
subjects affected / exposed	24 / 3587 (0.67%)	8 / 3587 (0.22%)	
occurrences causally related to treatment / all	0 / 27	1 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
URINARY TRACT INFECTION			
subjects affected / exposed	12 / 3587 (0.33%)	20 / 3587 (0.56%)	
occurrences causally related to treatment / all	0 / 14	0 / 22	
deaths causally related to treatment / all	0 / 0	0 / 0	
SEPSIS			
subjects affected / exposed	5 / 3587 (0.14%)	10 / 3587 (0.28%)	
occurrences causally related to treatment / all	0 / 5	0 / 10	
deaths causally related to treatment / all	0 / 1	0 / 2	
SEPTIC SHOCK			

subjects affected / exposed	4 / 3587 (0.11%)	8 / 3587 (0.22%)	
occurrences causally related to treatment / all	0 / 4	0 / 8	
deaths causally related to treatment / all	0 / 3	0 / 5	
BRONCHITIS			
subjects affected / exposed	4 / 3587 (0.11%)	7 / 3587 (0.20%)	
occurrences causally related to treatment / all	0 / 4	1 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
LOCALISED INFECTION			
subjects affected / exposed	4 / 3587 (0.11%)	6 / 3587 (0.17%)	
occurrences causally related to treatment / all	0 / 4	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
GANGRENE			
subjects affected / exposed	3 / 3587 (0.08%)	6 / 3587 (0.17%)	
occurrences causally related to treatment / all	0 / 3	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
GASTROENTERITIS			
subjects affected / exposed	7 / 3587 (0.20%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 7	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
RESPIRATORY TRACT INFECTION			
subjects affected / exposed	5 / 3587 (0.14%)	4 / 3587 (0.11%)	
occurrences causally related to treatment / all	0 / 5	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
BRONCHOPNEUMONIA			
subjects affected / exposed	5 / 3587 (0.14%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
LOWER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	5 / 3587 (0.14%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
OSTEOMYELITIS			

subjects affected / exposed	2 / 3587 (0.06%)	5 / 3587 (0.14%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
APPENDICITIS			
subjects affected / exposed	3 / 3587 (0.08%)	3 / 3587 (0.08%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
POSTOPERATIVE WOUND INFECTION			
subjects affected / exposed	4 / 3587 (0.11%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
WOUND INFECTION			
subjects affected / exposed	4 / 3587 (0.11%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
ERYSIPELAS			
subjects affected / exposed	0 / 3587 (0.00%)	5 / 3587 (0.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
LUNG INFECTION			
subjects affected / exposed	3 / 3587 (0.08%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 3	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
DENGUE FEVER			
subjects affected / exposed	4 / 3587 (0.11%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
DIVERTICULITIS			
subjects affected / exposed	3 / 3587 (0.08%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PYELONEPHRITIS ACUTE			

subjects affected / exposed	3 / 3587 (0.08%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 5	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
SUBCUTANEOUS ABSCESS			
subjects affected / exposed	3 / 3587 (0.08%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ARTHRITIS BACTERIAL			
subjects affected / exposed	1 / 3587 (0.03%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
GASTROINTESTINAL INFECTION			
subjects affected / exposed	1 / 3587 (0.03%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
MEDIASTINITIS			
subjects affected / exposed	1 / 3587 (0.03%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
ORCHITIS			
subjects affected / exposed	0 / 3587 (0.00%)	3 / 3587 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
PYELONEPHRITIS			
subjects affected / exposed	2 / 3587 (0.06%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
STAPHYLOCOCCAL SEPSIS			
subjects affected / exposed	1 / 3587 (0.03%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
UPPER RESPIRATORY TRACT INFECTION			

subjects affected / exposed	1 / 3587 (0.03%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
UROSEPSIS			
subjects affected / exposed	1 / 3587 (0.03%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
ABSCESS			
subjects affected / exposed	1 / 3587 (0.03%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ABSCESS LIMB			
subjects affected / exposed	0 / 3587 (0.00%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
ABSCESS NECK			
subjects affected / exposed	1 / 3587 (0.03%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ACUTE TONSILLITIS			
subjects affected / exposed	2 / 3587 (0.06%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ANAL ABSCESS			
subjects affected / exposed	0 / 3587 (0.00%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
BACTERAEMIA			
subjects affected / exposed	1 / 3587 (0.03%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ENDOCARDITIS			

subjects affected / exposed	0 / 3587 (0.00%)	2 / 3587 (0.06%)		
occurrences causally related to treatment / all	0 / 0	0 / 2		
deaths causally related to treatment / all	0 / 0	0 / 1		
IMPLANT SITE INFECTION				
subjects affected / exposed	1 / 3587 (0.03%)	1 / 3587 (0.03%)		
occurrences causally related to treatment / all	0 / 1	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
INFECTED SKIN ULCER				
subjects affected / exposed	0 / 3587 (0.00%)	2 / 3587 (0.06%)		
occurrences causally related to treatment / all	0 / 0	0 / 4		
deaths causally related to treatment / all	0 / 0	0 / 0		
INFECTIVE EXACERBATION OF CHRONIC OBSTRUCTIVE AIRWAYS DISEASE				
subjects affected / exposed	0 / 3587 (0.00%)	2 / 3587 (0.06%)		
occurrences causally related to treatment / all	0 / 0	0 / 2		
deaths causally related to treatment / all	0 / 0	0 / 0		
INFLUENZA				
subjects affected / exposed	2 / 3587 (0.06%)	0 / 3587 (0.00%)		
occurrences causally related to treatment / all	0 / 2	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
PERIRECTAL ABSCESS				
subjects affected / exposed	1 / 3587 (0.03%)	1 / 3587 (0.03%)		
occurrences causally related to treatment / all	0 / 1	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
PERITONITIS				
subjects affected / exposed	2 / 3587 (0.06%)	0 / 3587 (0.00%)		
occurrences causally related to treatment / all	0 / 2	0 / 0		
deaths causally related to treatment / all	0 / 1	0 / 0		
PHARYNGITIS				
subjects affected / exposed	1 / 3587 (0.03%)	1 / 3587 (0.03%)		
occurrences causally related to treatment / all	0 / 1	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
TRACHEOBRONCHITIS				

subjects affected / exposed	2 / 3587 (0.06%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ABDOMINAL WALL INFECTION			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ACQUIRED IMMUNODEFICIENCY SYNDROME			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ACTINOMYCOSIS			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ATYPICAL PNEUMONIA			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
BACTERIAL SEPSIS			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
BONE TUBERCULOSIS			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
BREAST ABSCESS			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
BRONCHITIS BACTERIAL			

subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
BURSITIS INFECTIVE			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CANDIDA PNEUMONIA			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CANDIDA SEPSIS			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CELLULITIS OF MALE EXTERNAL GENITAL ORGAN			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CELLULITIS STREPTOCOCCAL			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CHEST WALL ABSCESS			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CYSTITIS			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CHOLECYSTITIS INFECTIVE			

subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
DEVICE RELATED INFECTION			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
DIABETIC FOOT INFECTION			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
EAR TUBERCULOSIS			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
ENDOMETRITIS			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ENDOCARDITIS BACTERIAL			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ENDOPHTHALMITIS			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
ESCHERICHIA BACTERAEMIA			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ESCHERICHIA URINARY TRACT INFECTION			

subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
GASTROENTERITIS ROTAVIRUS			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
GASTROENTERITIS VIRAL			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
GENITOURINARY TRACT INFECTION			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
GRAFT INFECTION			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HAEMATOMA INFECTION			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HERPES ZOSTER			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
INCISION SITE CELLULITIS			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HISTOPLASMOSIS			

subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
INTESTINAL GANGRENE			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
KLEBSIELLA SEPSIS			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
LIVER ABSCESS			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
LOWER RESPIRATORY TRACT INFECTION VIRAL			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
LUDWIG ANGINA			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
MASTOIDITIS			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
NASAL ABSCESS			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
NECROTISING FASCIITIS			

subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
NEUROCYSTICERCOSIS			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
OTITIS MEDIA CHRONIC			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PARONYCHIA			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PERIODONTITIS			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PERITONITIS BACTERIAL			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
PERITONSILLAR ABSCESS			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PILONIDAL CYST			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PNEUMONIA KLEBSIELLA			

subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
POST PROCEDURAL CELLULITIS			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
POST PROCEDURAL INFECTION			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
POST PROCEDURAL PNEUMONIA			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PSEUDOMEMBRANOUS COLITIS			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PULMONARY SEPSIS			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
PULMONARY TUBERCULOSIS			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PYONEPHROSIS			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SALPINGITIS			

subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
SCROTAL ABSCESS			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SKIN INFECTION			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SOFT TISSUE INFECTION			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
STAPHYLOCOCCAL BACTERAEMIA			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
STAPHYLOCOCCAL INFECTION			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
STERNITIS			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
STREPTOCOCCAL ABSCESS			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
TYPHOID FEVER			

subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
URETERITIS			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
URINARY TRACT INFECTION PSEUDOMONAL			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
VARICELLA			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
VIRAL INFECTION			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
VIRAL SINUSITIS			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
WOUND INFECTION STAPHYLOCOCCAL			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
HYPOGLYCAEMIA			
subjects affected / exposed	39 / 3587 (1.09%)	17 / 3587 (0.47%)	
occurrences causally related to treatment / all	20 / 42	6 / 18	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPERGLYCAEMIA			

subjects affected / exposed	8 / 3587 (0.22%)	10 / 3587 (0.28%)	
occurrences causally related to treatment / all	0 / 8	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
DEHYDRATION			
subjects affected / exposed	7 / 3587 (0.20%)	8 / 3587 (0.22%)	
occurrences causally related to treatment / all	0 / 8	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
DIABETES MELLITUS INADEQUATE CONTROL			
subjects affected / exposed	3 / 3587 (0.08%)	9 / 3587 (0.25%)	
occurrences causally related to treatment / all	0 / 4	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPOKALAEMIA			
subjects affected / exposed	2 / 3587 (0.06%)	4 / 3587 (0.11%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
DIABETES MELLITUS			
subjects affected / exposed	1 / 3587 (0.03%)	3 / 3587 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPERKALAEMIA			
subjects affected / exposed	3 / 3587 (0.08%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 3	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPOMAGNESAEMIA			
subjects affected / exposed	2 / 3587 (0.06%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	1 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
DIABETIC KETOACIDOSIS			
subjects affected / exposed	0 / 3587 (0.00%)	3 / 3587 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPONATRAEMIA			

subjects affected / exposed	1 / 3587 (0.03%)	2 / 3587 (0.06%)	
occurrences causally related to treatment / all	0 / 1	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
FLUID OVERLOAD			
subjects affected / exposed	2 / 3587 (0.06%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	2 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
DECREASED APPETITE			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
FLUID RETENTION			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPERPHOSPHATAEMIA			
subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPOCALCAEMIA			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
KETOACIDOSIS			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
METABOLIC ACIDOSIS			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
TYPE 2 DIABETES MELLITUS			

subjects affected / exposed	0 / 3587 (0.00%)	1 / 3587 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
OBESITY			
subjects affected / exposed	1 / 3587 (0.03%)	0 / 3587 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Aleglitazar	Placebo	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1514 / 3587 (42.21%)	1119 / 3587 (31.20%)	
Investigations			
WEIGHT INCREASED			
subjects affected / exposed	395 / 3587 (11.01%)	171 / 3587 (4.77%)	
occurrences (all)	417	180	
BLOOD CREATININE INCREASED			
subjects affected / exposed	231 / 3587 (6.44%)	93 / 3587 (2.59%)	
occurrences (all)	279	105	
Vascular disorders			
HYPERTENSION			
subjects affected / exposed	165 / 3587 (4.60%)	183 / 3587 (5.10%)	
occurrences (all)	182	197	
Cardiac disorders			
ANGINA PECTORIS			
subjects affected / exposed	220 / 3587 (6.13%)	223 / 3587 (6.22%)	
occurrences (all)	253	258	
General disorders and administration site conditions			
NON−CARDIAC CHEST PAIN			
subjects affected / exposed	198 / 3587 (5.52%)	224 / 3587 (6.24%)	
occurrences (all)	248	265	
OEDEMA PERIPHERAL			
subjects affected / exposed	470 / 3587 (13.10%)	225 / 3587 (6.27%)	
occurrences (all)	544	266	

Metabolism and nutrition disorders			
HYPOGLYCAEMIA			
subjects affected / exposed	579 / 3587 (16.14%)	389 / 3587 (10.84%)	
occurrences (all)	1555	1004	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
25 February 2013	Added a study drug discontinuation criterion for patients who experienced a serious GI hemorrhage. This was done to address advice received from the Data Safety Monitoring Board. 25-Feb-2013

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported