Clinical trial results:
Apixaban Versus Acetylsalicylic Acid (ASA) to Prevent Stroke in Atrial Fibrillation Patients Who Have Failed or Are Unsuitable for Vitamin K Antagonist Treatment: A Randomized Double-blind Trial

Summary

EudraCT number	2007-001557-26
Trial protocol	GB FR SE BE DE FI ES DK CZ AT GR PL IT
Global end of trial date	25 May 2017

Results information

Result version number	v1 (current)
This version publication date	15 June 2018
First version publication date	15 June 2018

Trial information

Trial identification

Sponsor protocol code	CV185-048

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Bristol-Myers Squibb
Sponsor organisation address	Chaussée de la Hulpe 185, Brussels, Belgium, 1170
Public contact	EU Study Start-Up Unit, Bristol-Myers Squibb International Corporation, Clinical.Trials@bms.com
Scientific contact	Bristol-Myers Squibb Study Director, Bristol-Myers Squibb, Clinical.Trials@bms.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	25 May 2017
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	25 May 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The purpose of this study is to determine whether apixaban is more effective than acetylsalicylic acid in the prevention of strokes associated with subjects with atrial fibrillation. The safety of this treatment was also studied.

Three participants were missing age information from all study demographic tables, with no clear explanation about why data was missing. Because the system does not allow us to note missing information, the three participants of unknown age were added to the "Elderly (From 65-84 years)" age category.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and in compliance with all International Conference on Harmonization Good Clinical Practice Guidelines. All the local regulatory requirements pertinent to safety of trial subjects were followed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	31 August 2007
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Canada: 325
Country: Number of subjects enrolled	United States: 645
Country: Number of subjects enrolled	Argentina: 307
Country: Number of subjects enrolled	Brazil: 494
Country: Number of subjects enrolled	Chile: 125
Country: Number of subjects enrolled	Colombia: 50
Country: Number of subjects enrolled	Mexico: 394
Country: Number of subjects enrolled	Austria: 33
Country: Number of subjects enrolled	Belgium: 130
Country: Number of subjects enrolled	Czech Republic: 182
Country: Number of subjects enrolled	Denmark: 23
Country: Number of subjects enrolled	Finland: 61
Country: Number of subjects enrolled	France: 87
Country: Number of subjects enrolled	Germany: 369
Country: Number of subjects enrolled	Greece: 28
Country: Number of subjects enrolled	Israel: 126

Country: Number of subjects enrolled	Italy: 119
Country: Number of subjects enrolled	Norway: 17
Country: Number of subjects enrolled	Poland: 215
Country: Number of subjects enrolled	Russian Federation: 775
Country: Number of subjects enrolled	South Africa: 147
Country: Number of subjects enrolled	Spain: 29
Country: Number of subjects enrolled	Sweden: 107
Country: Number of subjects enrolled	Turkey: 30
Country: Number of subjects enrolled	United Kingdom: 123
Country: Number of subjects enrolled	Ukraine: 212
Country: Number of subjects enrolled	Australia: 56
Country: Number of subjects enrolled	China: 256
Country: Number of subjects enrolled	Hong Kong: 44
Country: Number of subjects enrolled	India: 233
Country: Number of subjects enrolled	Indonesia: 140
Country: Number of subjects enrolled	Malaysia: 122
Country: Number of subjects enrolled	Philippines: 134
Country: Number of subjects enrolled	Singapore: 47
Country: Number of subjects enrolled	Korea, Democratic People's Republic of: 145
Country: Number of subjects enrolled	Taiwan: 91
Worldwide total number of subjects	6421
EEA total number of subjects	1523

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)	1944
From 65 to 84 years	4010
85 years and over	467

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total 6421 subjects were enrolled in the study. Of these, 5598 were randomized (2807 to apixaban and 2791 to acetylsalicylic acid). Most (435) of the subjects who were not randomized (823) no longer met study criteria. Of those randomized, 5578 received treatment (2798 with apixaban, and 2780 with acetylsalicylic acid).

Period 1

Period 1 title	Randomization
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Apixaban, 2.5 or 5 mg Twice Daily

Arm description:

Patients received 5 mg of apixaban twice daily. Participants who fulfilled any 2 of the following criteria at baseline received apixaban, 2.5 mg twice daily: age older than 80 years, body weight of 60 kg or less, Serum creatinine level ≥1.5 mg/dL. Participants randomized to the 2.5 mg twice daily dose of apixaban continued on this dose throughout the study even if they no longer fulfilled the previous criteria.

Arm type	Experimental
Investigational medicinal product name	Apixaban 5.0 mg oral tablets BID
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

5.0 mg twice daily

Investigational medicinal product name	Apixaban 2.5 mg oral tablets BID
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

2.5 mg oral tablets twice daily

Arm title	Acetylsalicylic Acid, 81-324 mg Once Daily

Arm description:

Patients received 81 to 324 mg of acetylsalicylic acid once daily, with dosage based on investigator discretion Participants who completed the double-blind treatment period and met eligibility criteria had the option of enrolling in the Long Term Open Label Extension to receive open-label apixaban.

Arm type	Active comparator
Investigational medicinal product name	ASA 81 mg oral tablets BID
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

ASA 81 mg oral tablets twice daily

Number of subjects in period 1[1]	Apixaban, 2.5 or 5 mg Twice Daily	Acetylsalicylic Acid, 81-324 mg Once Daily
Started	2807	2791
Completed	2798	2780
Not completed	9	11
>=1 reason assigned per patient	9	11

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: 6421 subjects were enrolled in the trial, of those 5578 received treatment.

Period 2

Period 2 title	Double Blind
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Carer, Data analyst, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Apixaban, 2.5 or 5 mg Twice Daily

Arm description:

Patients received 5 mg of apixaban twice daily. Participants who fulfilled any 2 of the following criteria at baseline received apixaban, 2.5 mg twice daily: age older than 80 years, body weight of 60 kg or less, Serum creatinine level ≥1.5 mg/dL. Participants randomized to the 2.5 mg twice daily dose of apixaban continued on this dose throughout the study even if they no longer fulfilled the previous criteria.

Arm type	Experimental
Investigational medicinal product name	Apixaban 5.0 mg oral tablets BID
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

5.0 mg twice daily

Investigational medicinal product name	Apixaban 2.5 mg oral tablets BID
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

2.5 mg oral tablets twice daily

Arm title	Acetylsalicylic Acid, 81-324 mg Once Daily

Arm description:

Patients received 81 to 324 mg of acetylsalicylic acid once daily, with dosage based on investigator discretion Participants who completed the double-blind treatment period and met eligibility criteria had the option of enrolling in the Long Term Open Label Extension to receive open-label apixaban.

Arm type	Active comparator
Investigational medicinal product name	ASA 81 mg oral tablets BID
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

ASA 81 mg oral tablets twice daily

Number of subjects in period 2	Apixaban, 2.5 or 5 mg Twice Daily	Acetylsalicylic Acid, 81-324 mg Once Daily
Started	2798	2780
Completed	2249	2214
Not completed	549	566
>=1 reason assigned per patient	549	566

Period 3

Period 3 title	Open Label
Is this the baseline period?	No
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Arm title	Open Label Apixaban, 2.5 or 5 mg Twice Daily

Arm description:

Participants who completed the double-blind treatment period and met eligibility criteria had the option of enrolling in the Long Term Open Label Extension to receive open-label apixaban.

Arm type	Experimental
Investigational medicinal product name	Apixaban 5.0 mg oral tablets BID
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

5.0 mg twice daily

Investigational medicinal product name	Apixaban 2.5 mg oral tablets BID
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

2.5 mg oral tablets twice daily

Number of subjects in period 3[2]	Open Label Apixaban, 2.5 or 5 mg Twice Daily
Started	3275
Completed	2264
Not completed	1011
>=1 reason assigned per patient	1011

Notes:

[2] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.

Justification: 1207 subjects discontinued the Double Blind treatment period 3275 entered the Open Label period. Subjects from both arms in the Double Blind treatment period were eligible to participate in the Open Label period.

Baseline characteristics

Reporting groups	
Reporting group title	Apixaban, 2.5 or 5 mg Twice Daily
Reporting group description:	
Patients received 5 mg of apixaban twice daily. Participants who fulfilled any 2 of the following criteria at baseline received apixaban, 2.5 mg twice daily: age older than 80 years, body weight of 60 kg or less, Serum creatinine level ≥1.5 mg/dL. Participants randomized to the 2.5 mg twice daily dose of apixaban continued on this dose throughout the study even if they no longer fulfilled the previous criteria.	
Reporting group title	Acetylsalicylic Acid, 81-324 mg Once Daily
Reporting group description:	
Patients received 81 to 324 mg of acetylsalicylic acid once daily, with dosage based on investigator discretion Participants who completed the double-blind treatment period and met eligibility criteria had the option of enrolling in the Long Term Open Label Extension to receive open-label apixaban.	

Reporting group values	Apixaban, 2.5 or 5 mg Twice Daily	Acetylsalicylic Acid, 81-324 mg Once Daily	Total
Number of subjects	2807	2791	5598
Age, Customized Units: Subjects			
< 65 years	855	865	1720
>=65 but <75 years	1049	938	1987
>=75 years	903	988	1891
Age Continuous Units: years			
arithmetic mean	69.7	70.0	
standard deviation	± 9.44	± 9.71	-
Sex: Female, Male Units: Subjects			
Female	1147	1174	2321
Male	1660	1617	3277
Race/Ethnicity, Customized Units: Subjects			
American Indian or Alaska Native	6	6	12
Asian	541	544	1085
Native Hawaiian or Other Pacific Islander	3	1	4
Black or African American	10	26	36
White	2221	2178	4399
Other	26	36	62
Number of Participants by Number of Risk Factors for Stroke Units: Subjects			
1 or fewer	1085	1077	2162
2 or more	1722	1714	3436

End points

End points reporting groups

Reporting group title	Apixaban, 2.5 or 5 mg Twice Daily

Reporting group description:

Patients received 5 mg of apixaban twice daily. Participants who fulfilled any 2 of the following criteria at baseline received apixaban, 2.5 mg twice daily: age older than 80 years, body weight of 60 kg or less, Serum creatinine level ≥1.5 mg/dL. Participants randomized to the 2.5 mg twice daily dose of apixaban continued on this dose throughout the study even if they no longer fulfilled the previous criteria.

Reporting group title	Acetylsalicylic Acid, 81-324 mg Once Daily

Reporting group description:

Patients received 81 to 324 mg of acetylsalicylic acid once daily, with dosage based on investigator discretion Participants who completed the double-blind treatment period and met eligibility criteria had the option of enrolling in the Long Term Open Label Extension to receive open-label apixaban.

Reporting group title	Apixaban, 2.5 or 5 mg Twice Daily

Reporting group description:

Patients received 5 mg of apixaban twice daily. Participants who fulfilled any 2 of the following criteria at baseline received apixaban, 2.5 mg twice daily: age older than 80 years, body weight of 60 kg or less, Serum creatinine level ≥1.5 mg/dL. Participants randomized to the 2.5 mg twice daily dose of apixaban continued on this dose throughout the study even if they no longer fulfilled the previous criteria.

Reporting group title	Acetylsalicylic Acid, 81-324 mg Once Daily

Reporting group description:

Patients received 81 to 324 mg of acetylsalicylic acid once daily, with dosage based on investigator discretion Participants who completed the double-blind treatment period and met eligibility criteria had the option of enrolling in the Long Term Open Label Extension to receive open-label apixaban.

Reporting group title	Open Label Apixaban, 2.5 or 5 mg Twice Daily

Reporting group description:

Participants who completed the double-blind treatment period and met eligibility criteria had the option of enrolling in the Long Term Open Label Extension to receive open-label apixaban.

Primary: Event Rate of Stroke/Systemic Embolism During the Intended-treatment Period

End point title	Event Rate of Stroke/Systemic Embolism During the Intended-treatment Period

End point description:

Event rate=percent of participants with an event divided by the total participants in the arm. Intended-treatment period=date of randomization to the efficacy cutoff date, which was to be the date on which at least 226 unrefuted original primary efficacy events occurred (date revised to May 28, 2010 following cessation of study for superior efficacy.)

End point type	Primary

End point timeframe:

Randomization to efficacy cutoff date of May 28, 2010 (date revised following cessation of study for superior efficacy)

End point values	Apixaban, 2.5 or 5 mg Twice Daily	Acetylsalicylic Acid, 81-324 mg Once Daily		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2807	2791		
Units: Percentage of events				
number (not applicable)				

Stroke/Systemic Embolism Event Rate (%/yr)	1.62	3.63		

Statistical analyses

Statistical analysis title	Stroke/Systemic Embolism
Comparison groups	Apixaban, 2.5 or 5 mg Twice Daily v Acetylsalicylic Acid, 81-324 mg Once Daily
Number of subjects included in analysis	5598
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.45
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.32
upper limit	0.62

Secondary: Event Rate for the Composite of Stroke of any type, Systemic Embolism, Myocardial Infarction, or Vascular Death during the double-blind treatment period

End point title	Event Rate for the Composite of Stroke of any type, Systemic Embolism, Myocardial Infarction, or Vascular Death during the double-blind treatment period

End point description:

Event rate=percent of participants with an event divided by the total participants in the arm.

End point type	Secondary

End point timeframe:

Randomization to efficacy cutoff date of May 28, 2010 (date revised following cessation of study for superior efficacy)

End point values	Apixaban, 2.5 or 5 mg Twice Daily	Acetylsalicylic Acid, 81-324 mg Once Daily		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2807	2791		
Units: Percentage of events per year				
number (not applicable)				
Vascular death (n=84, 96) Event Rate (%/yr)	4.21	6.35		

Statistical analyses

Statistical analysis title	Vascular Death
Comparison groups	Apixaban, 2.5 or 5 mg Twice Daily v Acetylsalicylic Acid, 81-324 mg Once Daily
Number of subjects included in analysis	5598
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.00026
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.66
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.53
upper limit	0.83

Secondary: Event Rate of All-cause Death; Net Clinical Benefit-Composite of Stroke, Systemic Embolism, Myocardial Infarction, Vascular Death, and Major Bleeding; and Vascular Death

End point title	Event Rate of All-cause Death; Net Clinical Benefit-Composite of Stroke, Systemic Embolism, Myocardial Infarction, Vascular Death, and Major Bleeding; and Vascular Death
End point description:	
Event rate=percent of participants with an event divided by the total participants in the arm.	
End point type	Secondary
End point timeframe:	
Randomization to efficacy cutoff date of May 28, 2010 (date revised following cessation of study for superior efficacy)	

End point values	Apixaban, 2.5 or 5 mg Twice Daily	Acetylsalicylic Acid, 81-324 mg Once Daily		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2807	2791		
Units: Percentage of events per year				
number (not applicable)				
All-cause death (n=111, 140)|	3.51	4.42		
Net clinical benefit (n=163, 220)|	5.23	7.13		
Vascular death (n=84, 96)|	2.65	3.03		

Statistical analyses

Statistical analysis title	All-Cause Death
Comparison groups	Apixaban, 2.5 or 5 mg Twice Daily v Acetylsalicylic Acid, 81-324 mg Once Daily

Number of subjects included in analysis	5598
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.06782
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.79
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.62
upper limit	1.02

Statistical analysis title	Net-Clinical Benefit
Statistical analysis description:	
Composite of Major Vascular Events and Major Bleeding - net clinical benefit	
Comparison groups	Apixaban, 2.5 or 5 mg Twice Daily v Acetylsalicylic Acid, 81-324 mg Once Daily
Number of subjects included in analysis	5598
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0028
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.73
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.6
upper limit	0.9

Statistical analysis title	Vascular Death
Comparison groups	Apixaban, 2.5 or 5 mg Twice Daily v Acetylsalicylic Acid, 81-324 mg Once Daily
Number of subjects included in analysis	5598
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.36586
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.87
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.65
upper limit	1.17

Secondary: Event Rates for Major Bleeding, Major or Clinically Relevant Nonmajor (CNRM) Bleeding, and All Bleeding in the Double-blind Period

End point title	Event Rates for Major Bleeding, Major or Clinically Relevant Nonmajor (CNRM) Bleeding, and All Bleeding in the Double-blind Period

End point description:

Event rate=percent of participants with an event divided by the total participants in the arm.

End point type	Secondary

End point timeframe:

First dose of study drug (Day 1) to the earlier of a patient's discontinuation of double-blind study drug or the attainment of at least 226 primary efficacy events up to May 28, 2010

End point values	Apixaban, 2.5 or 5 mg Twice Daily	Acetylsalicylic Acid, 81-324 mg Once Daily		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2798	2780		
Units: Percentage of events per year				
number (not applicable)				
Major bleeding Event Rate (%/yr)	1.41	0.92		
Major or CRNM bleeding Event Rate (%/yr)	4.46	3.24		
All bleeding Event Rate (%/yr)	10.85	8.32		

Statistical analyses

Statistical analysis title	Major Bleeding
Comparison groups	Apixaban, 2.5 or 5 mg Twice Daily v Acetylsalicylic Acid, 81-324 mg Once Daily
Number of subjects included in analysis	5578
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.0716
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	1.54
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.96
upper limit	2.45

	All Bleeding

Statistical analysis title	
Comparison groups	Apixaban, 2.5 or 5 mg Twice Daily v Acetylsalicylic Acid, 81-324 mg Once Daily
Number of subjects included in analysis	5578
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.0017
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	1.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.1
upper limit	1.53

Statistical analysis title	Major or CRNM Bleeding
Comparison groups	Apixaban, 2.5 or 5 mg Twice Daily v Acetylsalicylic Acid, 81-324 mg Once Daily
Number of subjects included in analysis	5578
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.0144
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	1.38
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.07
upper limit	1.78

Secondary: Rate of Unrefuted Bleeding From First Dose of Double-blind Study Drug to First Occurence of Unrefuted Bleeding During the Double-blind Treatment Period

End point title	Rate of Unrefuted Bleeding From First Dose of Double-blind Study Drug to First Occurence of Unrefuted Bleeding During the Double-blind Treatment Period

End point description:

Event rate=percent of participants with an event divided by the total participants in the arm.

End point type	Secondary

End point timeframe:

Day 1 to first bleeding event up to efficacy cutoff date of May 28, 2010 (date revised following cessation of study for superior efficacy)

End point values	Apixaban, 2.5 or 5 mg Twice Daily	Acetylsalicylic Acid, 81-324 mg Once Daily		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2798	2780		
Units: Percentage of events per year				
number (not applicable)	10.85	8.32		

Statistical analyses

Statistical analysis title	Unrefuted Bleeding
Comparison groups	Apixaban, 2.5 or 5 mg Twice Daily v Acetylsalicylic Acid, 81-324 mg Once Daily
Number of subjects included in analysis	5578
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.0017
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	1.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.1
upper limit	1.53

Secondary: Number of Participants With Serious Adverse Events (SAEs), Adverse Events (AEs), Bleeding AEs, Discontinuations Due to AEs, and Death as Outcome

End point title	Number of Participants With Serious Adverse Events (SAEs), Adverse Events (AEs), Bleeding AEs, Discontinuations Due to AEs, and Death as Outcome

End point description:

AE=any new unfavorable symptom, sign, or disease or worsening of a preexisting condition that may not have a causal relationship with treatment. SAE=a medical event that at any dose results in death, persistent or significant disability/incapacity, or drug dependency/abuse; is life-threatening, an important medical event, or a congenital anomaly/birth defect; or requires or prolongs hospitalization.

End point type	Secondary

End point timeframe:

First dose of study drug (Day 1) to 30 days after last dose of blinded study drug

End point values	Apixaban, 2.5 or 5 mg Twice Daily	Acetylsalicylic Acid, 81-324 mg Once Daily		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2798	2780		
Units: Participants				
AEs	1833	1925		

SAEs	657	804		
Bleeding AEs	281	259		
Discontinuations due to AE	266	362		
Deaths	91	115		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Laboratory Test Results Meeting the Criteria for Marked Abnormality (part 1 of 3)

End point title	Number of Participants With Laboratory Test Results Meeting the Criteria for Marked Abnormality (part 1 of 3)

End point description:

BL=baseline, LLN=lower limit of normal, ULN=upper limit of normal. Hemoglobin (g/dL), low: BL>2 or value ≤8; hematocrit(%), low: <0.75*BL; erythrocytes (*10^6 cells/µL), low: <0.75*BL; platelet count (*10^9 cells/L),low: <100*10^9 cells/L; leukocytes (*10^3 cells/µL), low if <0.8*BL and BL<LLN or <LLN and BL >ULN or <0.75*LLN when BL is missing or LLN ≤BL≤ ULN, high if >1.2*BL and BL>ULN or >ULN when BL and BL<LLN or >1.25*ULN when BL is missing or LLN≤BL≤ULN; neutrophils (absolute), low: <1.0*10^3 cells/µL; eosinophils (absolute), high: >0.750*10^3 cells/µL; basophils (absolute), high: >0.4*10^3 cells/µL; monocytes (absolute), high: 2*10^3 cells/µL; lymphocytes (absolute), low if <0.75*10^3 cells/µL, high if >7.50*10^3 cells/µL; ALP (U/L), high: 2*ULN; AST (U/L), high: 3*ULN; AST (U/L), high: 3*ULN; bilirubin, total (mg/dL), high: >2*ULN; bilirubin, direct (mg/dL), high: 1.5*ULN; BUN (mg/dL), high:>2*ULN; creatinine (mg/dL), high: >1.5*ULN.

End point type	Secondary

End point timeframe:

First dose of study drug (Day 1) to 30 days after last dose of blinded study drug

End point values	Apixaban, 2.5 or 5 mg Twice Daily	Acetylsalicylic Acid, 81-324 mg Once Daily		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2798	2780		
Units: Participants				
Hemoglobin, low (n=1956, 1893)|	131	120		
Hemoglobin, high (n=1956, 1893)|	0	0		
Hematocrit, low (n=1728, 1687)|	13	9		
Hematocrit,high (n=1728, 1687)	0	0		
Erythrocytes, low (n=1728, 1687)|	12	12		
Erythrocytes, high (n=1728, 1687)|	0	0		
Platelet count, low (n=2148, 2098)|	7	10		
Platelet count, high (n=2148, 2098)|	0	0		
Leukocytes, low (n=1738, 1698)|	12	14		
Leukocytes, high (n=1738, 1698)|	14	18		
Neutrophils (absolute), low (n=2170, 2138)|	2	1		
Neutrophils (absolute), high (n=2170, 2138)|	0	0		
Eosinophils (absolute), low (n=2170, 2138)|	0	0		

Eosinophils (absolute), high (n=2170, 2138)|	48	68		
Basophils (absolute), low (n=2170, 2138)|	0	0		
Basophils (absolute), high (n=2170, 2138)|	0	0		
Monocytes (absolute), low (n=2170, 2138)|	0	0		
Monocytes (absolute), high (n=2170, 2138)|	0	2		
Lymphocytes (absolute), low (n=2170, 2138)|	52	62		
Lymphocytes (absolute), high (n=2170, 2138)|	4	5		
Alkaline phosphatase (ALP), low (n=2781, 2758)|	0	0		
ALP, high (n=2781, 2758)|	34	27		
Aspartate phosphatase (AST), low (n=2779, 2753)|	0	0		
AST, high (n=2779, 2753)|	28	33		
Alanine aminotransferase (ALT),low(n=2779,2753)	0	0		
ALT, high (n=2779, 2753)|	23	31		
Bilirubin (total), low (n=2781, 2758)|	0	0		
Bilirubin (total), high (n=2781, 2758)|	30	43		
Bilirubin (direct), low (n=2773, 2750)|	0	0		
Bilirubin (direct), high (n=2773, 2750)|	241	248		
Blood urea nitrogen (BUN), low (n=2201, 2172)|	0	0		
BUN, high (n=2201, 2172)|	42	50		
Creatinine, low (n=2209, 2178)|	0	0		
Creatinine, high (n=2209, 2178)|	67	71		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Laboratory Test Results Meeting the Criteria for Marked Abnormality (part 2 of 3)

End point title	Number of Participants With Laboratory Test Results Meeting the Criteria for Marked Abnormality (part 2 of 3)

End point description:

LLN=lower limit of normal; ULN=upper limit of normal; BL=baseline. Sodium, serum (mEq/L):low if <0.95*BL and BL<LLN or <LLN and BL>ULN or <0.95*LLN when BL missing or LLN ≤BL≤ULN, high if >1.05*BL and BL>ULN or >ULN and BL<LLN or >1.05*ULN when BL missing or LLN≤BL≤ULN; potassium(mEq/L):low if <0.90*BL and BL<LLN or <LLN and BL>ULN or <0.90*LLN if BL missing or LLN≤BL≤ULN, high if >1.10*BL and BL>ULN or>ULN and BL<LLN or >1.10*ULN when BL missing or LLN≤BL≤ULN; chloride(mEq/L):low if <0.90*BL and BL<LLN or <LLN and BL>ULN or <0.90*LLN if BL missing or LLN≤BL ≤ULN, high if >1.10*BL and BL>ULN or >ULN and BL<LLN or >1.10* ULN if BL missing or LLN≤BL≤ULN; calcium(mg/dL):low if <0.75*BL and BL<LLN or <LLN and BL>ULN or <0.80*LLN if BL missing or LLN≤BL≤ULN, high if >1.25*BL and BL>ULN or >ULN if BL<LLN or >1.20*ULN if BL missing or LLN≤BL≤ULN ; bicarbonate(mEq/L):low if <0.75*BL when BL<LLN or <LLN when BL>ULN or <0.75*LLN if BL missing or LLN≤BL≤ULN, high if >1.25*BL when BL>ULN or >ULN

End point type	Secondary

End point timeframe:

First dose of study drug (Day 1) to 30 days after last dose of blinded study drug

End point values	Apixaban, 2.5 or 5 mg Twice Daily	Acetylsalicylic Acid, 81-324 mg Once Daily		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2798	2780		
Units: Participants				
Sodium (serum), low (n=1768, 1740)|	2	6		
Sodium (serum), high (n=1768, 1740)|	1	2		
Potassium (serum), low (n=1763, 1737)|	6	8		
Potassium (serum), high (n=1763, 1737)|	20	28		
Chloride (serum), low (n=1768, 1740)|	0	3		
Chloride (serum), high (n=1768, 1740)|	0	1		
Calcium (total), low (n=106, 109)|	0	0		
Calcium (total), high (n=106, 109)|	0	0		
Bicarbonate, low (n=1664, 1619)|	0	0		
Bicarbonate, high (n=1664, 1619)|	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Laboratory Test Results Meeting the Criteria for Marked Abnormality (part 3 of 3)

End point title	Number of Participants With Laboratory Test Results Meeting the Criteria for Marked Abnormality (part 3 of 3)

End point description:

ULN=upper limit of normal; LLN=lower limit ofnormal; BL=baseline. Creatine kinase (U/L), high:>5*ULN; protein, total(g/L):low if <0.90*BL when BL<LLN or <LLN when B >ULN or <0.90*LLN when BL is missing or LLN≤BL≤ULN, high if >1.10*BL if BL>ULN or >ULN when BL<LLN or >1.10*ULN if BL missing or LLN≤BL≤ULN.Protein,total(g/L): low if <0.90*BL if BL<LLN or <LLN if BL>ULN or <0.90*LLN if BL missing or LLN≤BL≤ULN, high if >1.10*BL if BL>ULN or >ULN if BL<LLN or >1.10*ULN if BL or LLN≤BL≤ULN; glucose, serum fasting (mg/dL): low if <0.8*BL if BL<LLN or <LLN when BL>ULN or <0.8*LLN when BL missing or LLN≤BL≤ULN, high if >2*BL when BL>ULN or >ULN when BL<LLN or >1.5*ULN if BL missing or LLN≤BL≤ULN; uric acid (mg/dL), high: >2*BL and BL>ULN or>1.5*ULN when BL missing or BL≤ULN; glucose, urine, high; protein, urine, high; blood, urine, high; leukocyte esterase, urine, high; RBC count, urine (Hpf), high; WBC count, urine (Hpf), high: ≥2 if BL=missing,=0 or =0.5 or if ≥3 if BL=1, or if ≥4 and BL≥2.

End point type	Secondary

End point timeframe:

First dose of study drug (Day 1) to 30 days after last dose of blinded study drug

End point values	Apixaban, 2.5 or 5 mg Twice Daily	Acetylsalicylic Acid, 81-324 mg Once Daily		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2798	2780		
Units: Participants				
Creatine kinase, low (n=2780, 2758)|	0	0		
Creatine kinase, high (n=2780, 2758)|	13	25		
Protein (total), low (n=103, 109)|	0	0		
Protein (total), high (n=103, 109)|	0	0		
Uric acid, low (n=386, 390)|	0	0		
Uric acid, high (n=386, 390)|	1	0		
Glucose (urine), low (n=2, 3)|	0	0		
Glucose (urine), high (n=2, 3)|	0	1		
Protein (urine), low (n=3, 5)|	0	0		
Protein (urine), high (n=3, 5)|	1	1		
Blood (urine), low (n=3, 5)|	0	0		
Blood (urine), high (n=3, 5)|	1	0		
Leukocyte esterase (urine), low (n=3,5)|	0	0		
Leukocyte esterase (urine), high (n=3,5)|	0	0		
Red blood cells (RBC) (urine), low (n=2,2)|	0	0		
RBC (urine), high (n=2,2)|	1	0		
White blood cells (urine), low (n=2,2)|	0	0		
WBC (urine), high (n=2,2)|	0	0		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
First dose of study drug (Day 1) to 30 days after last dose of study drug.	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	20.1

Reporting groups	
Reporting group title	DB-Apixaban
Reporting group description:	
Subjects received 5 milligram (mg) or 2.5 mg Apixaban orally as tablets (reduced dose for subjects deemed to be at increased risk of bleeding), twice a day (BID).	
Reporting group title	OL-Apixaban
Reporting group description:	
Subjects received 5 mg or 2.5 mg Apixaban orally as tablets (reduced dose for subjects deemed to be at increased risk of bleeding), BID.	
Reporting group title	DB-ASA
Reporting group description:	
Subjects received Acetylsalicylic Acid (ASA) 81 to 324 mg or matching placebo orally as tablet once a day.	

Serious adverse events	DB-Apixaban	OL-Apixaban	DB-ASA
Total subjects affected by serious adverse events			
subjects affected / exposed	679 / 2798 (24.27%)	1252 / 3275 (38.23%)	844 / 2780 (30.36%)
number of deaths (all causes)	111	265	140
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute myeloid leukaemia			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenocarcinoma			
subjects affected / exposed	1 / 2798 (0.04%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenocarcinoma gastric			

subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Adenocarcinoma of colon			
subjects affected / exposed	0 / 2798 (0.00%)	2 / 3275 (0.06%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adrenal adenoma			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angiosarcoma			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
B-Cell lymphoma			
subjects affected / exposed	0 / 2798 (0.00%)	2 / 3275 (0.06%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
B-Cell small lymphocytic lymphoma stage iv			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Basal cell carcinoma			
subjects affected / exposed	5 / 2798 (0.18%)	12 / 3275 (0.37%)	5 / 2780 (0.18%)
occurrences causally related to treatment / all	1 / 6	1 / 12	3 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Basosquamous carcinoma			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary neoplasm			

subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder cancer			
subjects affected / exposed	1 / 2798 (0.04%)	4 / 3275 (0.12%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 1	2 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder cancer stage 0, with cancer in situ			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder neoplasm			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bowen's disease			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain cancer metastatic			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Brain neoplasm			
subjects affected / exposed	0 / 2798 (0.00%)	4 / 3275 (0.12%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain neoplasm benign			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast cancer			

subjects affected / exposed	9 / 2798 (0.32%)	10 / 3275 (0.31%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	3 / 9	5 / 10	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Breast cancer metastatic			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial carcinoma			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	2 / 2780 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Carcinoid tumour of the caecum			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carcinoid tumour of the pancreas			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervix carcinoma stage 0			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangiocarcinoma			
subjects affected / exposed	0 / 2798 (0.00%)	2 / 3275 (0.06%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Cholesteatoma			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic lymphocytic leukaemia			

subjects affected / exposed	0 / 2798 (0.00%)	2 / 3275 (0.06%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon cancer			
subjects affected / exposed	2 / 2798 (0.07%)	6 / 3275 (0.18%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 2	1 / 6	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Colon cancer metastatic			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon neoplasm			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colorectal cancer			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diffuse large b-cell lymphoma			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endometrial cancer			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gallbladder cancer			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Gastric cancer			

subjects affected / exposed	1 / 2798 (0.04%)	3 / 3275 (0.09%)	2 / 2780 (0.07%)
occurrences causally related to treatment / all	1 / 1	1 / 3	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Gastrointestinal carcinoma			
subjects affected / exposed	1 / 2798 (0.04%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal stromal tumour			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic neoplasm malignant			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Hepatocellular carcinoma			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal adenocarcinoma			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intraductal papillary mucinous neoplasm			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intraocular melanoma			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Invasive ductal breast carcinoma			

subjects affected / exposed	0 / 2798 (0.00%)	2 / 3275 (0.06%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngeal cancer			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	2 / 2780 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leiomyoma			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leiomyosarcoma metastatic			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukaemia			
subjects affected / exposed	2 / 2798 (0.07%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Light chain disease			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Lip and/or oral cavity cancer			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lipoma			
subjects affected / exposed	1 / 2798 (0.04%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liposarcoma			

subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Lung adenocarcinoma			
subjects affected / exposed	0 / 2798 (0.00%)	2 / 3275 (0.06%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung adenocarcinoma metastatic			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung cancer metastatic			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Lung neoplasm			
subjects affected / exposed	0 / 2798 (0.00%)	2 / 3275 (0.06%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Lung neoplasm malignant			
subjects affected / exposed	4 / 2798 (0.14%)	17 / 3275 (0.52%)	5 / 2780 (0.18%)
occurrences causally related to treatment / all	1 / 4	8 / 18	2 / 5
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Lymph node cancer metastatic			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphoma			
subjects affected / exposed	1 / 2798 (0.04%)	2 / 3275 (0.06%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant melanoma			

subjects affected / exposed	1 / 2798 (0.04%)	2 / 3275 (0.06%)	2 / 2780 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant melanoma stage i			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningioma			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Metastases to abdominal cavity			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to bone			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to central nervous system			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to liver			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to pleura			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastatic neoplasm			

subjects affected / exposed	0 / 2798 (0.00%)	2 / 3275 (0.06%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Metastatic renal cell carcinoma			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myeloproliferative neoplasm			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm malignant			
subjects affected / exposed	1 / 2798 (0.04%)	2 / 3275 (0.06%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	1 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Neoplasm prostate			
subjects affected / exposed	1 / 2798 (0.04%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuroendocrine tumour			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-Hodgkin's lymphoma			
subjects affected / exposed	1 / 2798 (0.04%)	2 / 3275 (0.06%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-Hodgkin's lymphoma stage iii			

subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal adenocarcinoma			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal cancer metastatic			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Omentum neoplasm			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian cancer			
subjects affected / exposed	0 / 2798 (0.00%)	3 / 3275 (0.09%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic carcinoma			
subjects affected / exposed	0 / 2798 (0.00%)	6 / 3275 (0.18%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	2 / 7	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Paraneoplastic syndrome			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic neoplasm			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pituitary tumour benign			

subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Plasma cell myeloma			
subjects affected / exposed	0 / 2798 (0.00%)	2 / 3275 (0.06%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer			
subjects affected / exposed	7 / 2798 (0.25%)	13 / 3275 (0.40%)	12 / 2780 (0.43%)
occurrences causally related to treatment / all	2 / 7	6 / 14	2 / 12
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Prostate cancer metastatic			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer recurrent			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatic adenoma			
subjects affected / exposed	2 / 2798 (0.07%)	3 / 3275 (0.09%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	1 / 2	1 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal adenocarcinoma			
subjects affected / exposed	0 / 2798 (0.00%)	2 / 3275 (0.06%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal cancer			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	2 / 2780 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Rectal cancer metastatic			

subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal cancer			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal cancer stage ii			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal cancer stage iii			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal cell carcinoma			
subjects affected / exposed	1 / 2798 (0.04%)	2 / 3275 (0.06%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal neoplasm			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sebaceous carcinoma			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seborrhoeic keratosis			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin cancer			

subjects affected / exposed	0 / 2798 (0.00%)	3 / 3275 (0.09%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma			
subjects affected / exposed	2 / 2798 (0.07%)	7 / 3275 (0.21%)	4 / 2780 (0.14%)
occurrences causally related to treatment / all	4 / 5	2 / 8	1 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of skin			
subjects affected / exposed	3 / 2798 (0.11%)	4 / 3275 (0.12%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 3	2 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of the cervix			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Throat cancer			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thyroid adenoma			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsil cancer			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transitional cell carcinoma			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour haemorrhage			

subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureteric cancer metastatic			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine cancer			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine leiomyoma			
subjects affected / exposed	0 / 2798 (0.00%)	2 / 3275 (0.06%)	2 / 2780 (0.07%)
occurrences causally related to treatment / all	0 / 0	1 / 2	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vocal cord neoplasm			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Accelerated hypertension			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aneurysm			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic aneurysm			
subjects affected / exposed	0 / 2798 (0.00%)	2 / 3275 (0.06%)	2 / 2780 (0.07%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Aortic dissection			

subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic rupture			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Aortic stenosis			
subjects affected / exposed	2 / 2798 (0.07%)	3 / 3275 (0.09%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arterial disorder			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arterial occlusive disease			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arterial stenosis			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arterial thrombosis limb			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arteriosclerosis			
subjects affected / exposed	1 / 2798 (0.04%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arteriosclerosis obliterans			

subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Circulatory collapse			
subjects affected / exposed	0 / 2798 (0.00%)	2 / 3275 (0.06%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deep vein thrombosis			
subjects affected / exposed	2 / 2798 (0.07%)	3 / 3275 (0.09%)	6 / 2780 (0.22%)
occurrences causally related to treatment / all	1 / 2	2 / 3	3 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dry gangrene			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femoral artery embolism			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femoral artery occlusion			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	3 / 2780 (0.11%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematoma			
subjects affected / exposed	1 / 2798 (0.04%)	5 / 3275 (0.15%)	3 / 2780 (0.11%)
occurrences causally related to treatment / all	1 / 1	3 / 5	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage			
subjects affected / exposed	1 / 2798 (0.04%)	6 / 3275 (0.18%)	3 / 2780 (0.11%)
occurrences causally related to treatment / all	1 / 1	5 / 6	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			

subjects affected / exposed	4 / 2798 (0.14%)	13 / 3275 (0.40%)	9 / 2780 (0.32%)
occurrences causally related to treatment / all	3 / 4	4 / 13	4 / 10
deaths causally related to treatment / all	1 / 1	0 / 2	0 / 0
Hypertensive crisis			
subjects affected / exposed	6 / 2798 (0.21%)	3 / 3275 (0.09%)	3 / 2780 (0.11%)
occurrences causally related to treatment / all	1 / 6	1 / 4	3 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive emergency			
subjects affected / exposed	1 / 2798 (0.04%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	3 / 2798 (0.11%)	5 / 3275 (0.15%)	5 / 2780 (0.18%)
occurrences causally related to treatment / all	1 / 3	0 / 6	1 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypovolaemic shock			
subjects affected / exposed	0 / 2798 (0.00%)	2 / 3275 (0.06%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Intermittent claudication			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leriche syndrome			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphocele			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant hypertension			

subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orthostatic hypotension			
subjects affected / exposed	1 / 2798 (0.04%)	3 / 3275 (0.09%)	6 / 2780 (0.22%)
occurrences causally related to treatment / all	1 / 1	0 / 3	1 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pallor			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic venous thrombosis			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral arterial occlusive disease			
subjects affected / exposed	0 / 2798 (0.00%)	2 / 3275 (0.06%)	4 / 2780 (0.14%)
occurrences causally related to treatment / all	0 / 0	1 / 2	2 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral artery stenosis			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral artery thrombosis			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral embolism			
subjects affected / exposed	0 / 2798 (0.00%)	2 / 3275 (0.06%)	2 / 2780 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral ischaemia			

subjects affected / exposed	0 / 2798 (0.00%)	3 / 3275 (0.09%)	5 / 2780 (0.18%)
occurrences causally related to treatment / all	0 / 0	0 / 3	1 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral vascular disorder			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral venous disease			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Phlebitis			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Shock			
subjects affected / exposed	1 / 2798 (0.04%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 1	0 / 0
Subclavian artery stenosis			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Temporal arteritis			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombophlebitis			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombophlebitis superficial			

subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombosis			
subjects affected / exposed	1 / 2798 (0.04%)	1 / 3275 (0.03%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicose ulceration			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicose vein			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicose vein ruptured			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venous haemorrhage			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Venous insufficiency			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venous thrombosis			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	2 / 2780 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Abdominoplasty			

subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angioplasty			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anorectal operation			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic aneurysm repair			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic valve replacement			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicectomy			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign tumour excision			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder polypectomy			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bursa removal			

subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bursal operation			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cancer surgery			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac ablation			
subjects affected / exposed	2 / 2798 (0.07%)	1 / 3275 (0.03%)	2 / 2780 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac pacemaker battery replacement			
subjects affected / exposed	3 / 2798 (0.11%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac pacemaker insertion			
subjects affected / exposed	4 / 2798 (0.14%)	9 / 3275 (0.27%)	3 / 2780 (0.11%)
occurrences causally related to treatment / all	0 / 4	1 / 9	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac pacemaker removal			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac pacemaker replacement			
subjects affected / exposed	1 / 2798 (0.04%)	2 / 3275 (0.06%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardioversion			

subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid endarterectomy			
subjects affected / exposed	0 / 2798 (0.00%)	2 / 3275 (0.06%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cataract operation			
subjects affected / exposed	0 / 2798 (0.00%)	2 / 3275 (0.06%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chemotherapy			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystectomy			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	2 / 2780 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Choledochoenterostomy			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary angioplasty			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary arterial stent insertion			
subjects affected / exposed	0 / 2798 (0.00%)	2 / 3275 (0.06%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery bypass			

subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endarterectomy			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endovenous ablation			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Explorative laparotomy			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye operation			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fasciotomy			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gallbladder operation			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric bypass			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal tube insertion			

subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Genitourinary operation			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhoid operation			
subjects affected / exposed	1 / 2798 (0.04%)	1 / 3275 (0.03%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	1 / 1	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Heart valve operation			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	2 / 2780 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Heart valve replacement			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hernia repair			
subjects affected / exposed	1 / 2798 (0.04%)	2 / 3275 (0.06%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
High frequency ablation			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip arthroplasty			
subjects affected / exposed	2 / 2798 (0.07%)	9 / 3275 (0.27%)	2 / 2780 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 9	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip surgery			

subjects affected / exposed	1 / 2798 (0.04%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hospitalisation			
subjects affected / exposed	3 / 2798 (0.11%)	1 / 3275 (0.03%)	2 / 2780 (0.07%)
occurrences causally related to treatment / all	1 / 3	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis repair			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hysterectomy			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Implantable defibrillator insertion			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Implantable defibrillator replacement			
subjects affected / exposed	1 / 2798 (0.04%)	2 / 3275 (0.06%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incisional hernia repair			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia repair			
subjects affected / exposed	4 / 2798 (0.14%)	4 / 3275 (0.12%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 5	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal anastomosis			

subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Knee arthroplasty			
subjects affected / exposed	1 / 2798 (0.04%)	6 / 3275 (0.18%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 6	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Knee operation			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laparotomy			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lithotripsy			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver operation			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung operation			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mastectomy			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Medical device implantation			

subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Medical device removal			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mitral valve repair			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mitral valve replacement			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orchidectomy			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreaticoduodenectomy			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Papilloma excision			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Percutaneous coronary intervention			
subjects affected / exposed	2 / 2798 (0.07%)	0 / 3275 (0.00%)	2 / 2780 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral artery angioplasty			

subjects affected / exposed	1 / 2798 (0.04%)	3 / 3275 (0.09%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Plastic surgery to the face			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Proctocolectomy			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatic operation			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	2 / 2780 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal polypectomy			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rehabilitation therapy			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal stone removal			
subjects affected / exposed	1 / 2798 (0.04%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Salivary gland operation			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin graft			

subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin lesion removal			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin neoplasm excision			
subjects affected / exposed	1 / 2798 (0.04%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal fusion surgery			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tarsal tunnel decompression			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Therapeutic embolisation			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thromboembolectomy			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thyroid operation			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thyroidectomy			

subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toe amputation			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tooth extraction			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tracheostomy			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transfusion			
subjects affected / exposed	1 / 2798 (0.04%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 2	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transurethral prostatectomy			
subjects affected / exposed	1 / 2798 (0.04%)	1 / 3275 (0.03%)	4 / 2780 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 1	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureteral stent insertion			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urethral stent insertion			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine dilation and curettage			

subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular graft			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventriculo-Peritoneal shunt			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertebroplasty			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Weight loss diet			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wrist surgery			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Cephalhaematoma			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
General disorders and administration site conditions			
Adverse drug reaction			
subjects affected / exposed	0 / 2798 (0.00%)	3 / 3275 (0.09%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	1 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Asthenia			
subjects affected / exposed	4 / 2798 (0.14%)	9 / 3275 (0.27%)	2 / 2780 (0.07%)
occurrences causally related to treatment / all	1 / 4	2 / 9	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac death			
subjects affected / exposed	1 / 2798 (0.04%)	3 / 3275 (0.09%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 1	1 / 3	1 / 1
deaths causally related to treatment / all	0 / 1	1 / 3	1 / 1
Chest discomfort			
subjects affected / exposed	1 / 2798 (0.04%)	2 / 3275 (0.06%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain			
subjects affected / exposed	18 / 2798 (0.64%)	29 / 3275 (0.89%)	27 / 2780 (0.97%)
occurrences causally related to treatment / all	5 / 26	5 / 31	9 / 33
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Death			
subjects affected / exposed	20 / 2798 (0.71%)	48 / 3275 (1.47%)	16 / 2780 (0.58%)
occurrences causally related to treatment / all	9 / 20	17 / 48	5 / 16
deaths causally related to treatment / all	7 / 17	15 / 45	4 / 15
Device lead damage			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device malfunction			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device pacing issue			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Exercise tolerance decreased			

subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gait disturbance			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	2 / 2780 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	4 / 2798 (0.14%)	1 / 3275 (0.03%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Generalised oedema			
subjects affected / exposed	1 / 2798 (0.04%)	1 / 3275 (0.03%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Hernia			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hernia pain			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Implant site effusion			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incarcerated hernia			

subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malaise			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Medical device complication			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multi-Organ failure			
subjects affected / exposed	2 / 2798 (0.07%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 2	0 / 0	0 / 0
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 2798 (0.00%)	5 / 3275 (0.15%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Non-Cardiac chest pain			
subjects affected / exposed	3 / 2798 (0.11%)	2 / 3275 (0.06%)	6 / 2780 (0.22%)
occurrences causally related to treatment / all	0 / 3	0 / 2	1 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema			
subjects affected / exposed	1 / 2798 (0.04%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	2 / 2798 (0.07%)	7 / 3275 (0.21%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	1 / 2	0 / 7	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			

subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic mass			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral swelling			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	3 / 2798 (0.11%)	7 / 3275 (0.21%)	3 / 2780 (0.11%)
occurrences causally related to treatment / all	1 / 3	0 / 7	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden cardiac death			
subjects affected / exposed	3 / 2798 (0.11%)	6 / 3275 (0.18%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	1 / 3	3 / 6	1 / 1
deaths causally related to treatment / all	1 / 3	3 / 6	1 / 1
Sudden death			
subjects affected / exposed	13 / 2798 (0.46%)	36 / 3275 (1.10%)	15 / 2780 (0.54%)
occurrences causally related to treatment / all	4 / 13	8 / 36	5 / 15
deaths causally related to treatment / all	3 / 12	7 / 33	5 / 15
Suprapubic pain			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Swelling			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic inflammatory response syndrome			

subjects affected / exposed	1 / 2798 (0.04%)	1 / 3275 (0.03%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Unevaluable event			
subjects affected / exposed	0 / 2798 (0.00%)	2 / 3275 (0.06%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Social circumstances			
Activities of daily living impaired			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac assistance device user			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Physical assault			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Benign prostatic hyperplasia			
subjects affected / exposed	2 / 2798 (0.07%)	8 / 3275 (0.24%)	3 / 2780 (0.11%)
occurrences causally related to treatment / all	0 / 2	0 / 8	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast mass			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Menometrorrhagia			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metrorrhagia			
subjects affected / exposed	1 / 2798 (0.04%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postmenopausal haemorrhage			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatic hypoplasia			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatic obstruction			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatomegaly			
subjects affected / exposed	0 / 2798 (0.00%)	2 / 3275 (0.06%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spermatic cord disorder			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine polyp			
subjects affected / exposed	0 / 2798 (0.00%)	2 / 3275 (0.06%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vaginal haemorrhage			

subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute pulmonary oedema			
subjects affected / exposed	6 / 2798 (0.21%)	4 / 3275 (0.12%)	3 / 2780 (0.11%)
occurrences causally related to treatment / all	1 / 6	1 / 4	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 1
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute respiratory failure			
subjects affected / exposed	5 / 2798 (0.18%)	4 / 3275 (0.12%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	1 / 5	1 / 4	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Allergic bronchitis			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asphyxia			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Asthma			
subjects affected / exposed	6 / 2798 (0.21%)	5 / 3275 (0.15%)	4 / 2780 (0.14%)
occurrences causally related to treatment / all	3 / 6	1 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Atelectasis			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis chronic			

subjects affected / exposed	1 / 2798 (0.04%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchospasm			
subjects affected / exposed	1 / 2798 (0.04%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary disease			
subjects affected / exposed	12 / 2798 (0.43%)	25 / 3275 (0.76%)	11 / 2780 (0.40%)
occurrences causally related to treatment / all	2 / 12	9 / 37	3 / 17
deaths causally related to treatment / all	0 / 1	0 / 2	0 / 0
Cough			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	13 / 2798 (0.46%)	24 / 3275 (0.73%)	13 / 2780 (0.47%)
occurrences causally related to treatment / all	11 / 18	3 / 28	3 / 13
deaths causally related to treatment / all	1 / 1	0 / 1	0 / 0
Dyspnoea exertional			
subjects affected / exposed	0 / 2798 (0.00%)	4 / 3275 (0.12%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Emphysema			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis			
subjects affected / exposed	5 / 2798 (0.18%)	16 / 3275 (0.49%)	6 / 2780 (0.22%)
occurrences causally related to treatment / all	4 / 5	14 / 17	6 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			

subjects affected / exposed	3 / 2798 (0.11%)	6 / 3275 (0.18%)	4 / 2780 (0.14%)
occurrences causally related to treatment / all	3 / 3	6 / 7	2 / 4
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Haemothorax			
subjects affected / exposed	0 / 2798 (0.00%)	2 / 3275 (0.06%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hiccups			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperventilation			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 2798 (0.00%)	2 / 3275 (0.06%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung consolidation			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung disorder			
subjects affected / exposed	1 / 2798 (0.04%)	3 / 3275 (0.09%)	2 / 2780 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Lung infiltration			
subjects affected / exposed	1 / 2798 (0.04%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mediastinal mass			

subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orthopnoea			
subjects affected / exposed	1 / 2798 (0.04%)	2 / 3275 (0.06%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	2 / 2798 (0.07%)	6 / 3275 (0.18%)	4 / 2780 (0.14%)
occurrences causally related to treatment / all	0 / 3	0 / 6	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleurisy			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia aspiration			
subjects affected / exposed	3 / 2798 (0.11%)	3 / 3275 (0.09%)	2 / 2780 (0.07%)
occurrences causally related to treatment / all	1 / 3	1 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Pneumothorax			
subjects affected / exposed	3 / 2798 (0.11%)	0 / 3275 (0.00%)	2 / 2780 (0.07%)
occurrences causally related to treatment / all	0 / 4	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary artery thrombosis			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary congestion			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			

subjects affected / exposed	4 / 2798 (0.14%)	9 / 3275 (0.27%)	12 / 2780 (0.43%)
occurrences causally related to treatment / all	0 / 4	3 / 9	3 / 12
deaths causally related to treatment / all	0 / 1	1 / 1	0 / 0
Pulmonary fibrosis			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary hypertension			
subjects affected / exposed	1 / 2798 (0.04%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Pulmonary oedema			
subjects affected / exposed	2 / 2798 (0.07%)	4 / 3275 (0.12%)	2 / 2780 (0.07%)
occurrences causally related to treatment / all	1 / 2	1 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary vascular disorder			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory arrest			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Respiratory distress			
subjects affected / exposed	0 / 2798 (0.00%)	3 / 3275 (0.09%)	3 / 2780 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Respiratory failure			
subjects affected / exposed	4 / 2798 (0.14%)	5 / 3275 (0.15%)	12 / 2780 (0.43%)
occurrences causally related to treatment / all	2 / 4	1 / 6	2 / 12
deaths causally related to treatment / all	0 / 1	0 / 3	2 / 7
Sinus polyp			

subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sleep apnoea syndrome			
subjects affected / exposed	1 / 2798 (0.04%)	2 / 3275 (0.06%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Adjustment disorder			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alcohol abuse			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	2 / 2780 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alcohol withdrawal syndrome			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anxiety			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bipolar disorder			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bipolar i disorder			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Completed suicide			

subjects affected / exposed	0 / 2798 (0.00%)	2 / 3275 (0.06%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 2	0 / 0
Confusional state			
subjects affected / exposed	3 / 2798 (0.11%)	2 / 3275 (0.06%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	1 / 3	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	3 / 2780 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression			
subjects affected / exposed	2 / 2798 (0.07%)	3 / 3275 (0.09%)	2 / 2780 (0.07%)
occurrences causally related to treatment / all	1 / 2	0 / 3	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hallucination			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Insomnia			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental disorder			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Panic attack			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paranoia			

subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychotic disorder			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stress			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal ideation			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicide attempt			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
Lead dislodgement			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Acute hepatic failure			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bile duct stenosis			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bile duct stone			

subjects affected / exposed	1 / 2798 (0.04%)	3 / 3275 (0.09%)	3 / 2780 (0.11%)
occurrences causally related to treatment / all	1 / 1	1 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
subjects affected / exposed	2 / 2798 (0.07%)	3 / 3275 (0.09%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	3 / 3	1 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis acute			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Cholecystitis			
subjects affected / exposed	6 / 2798 (0.21%)	4 / 3275 (0.12%)	7 / 2780 (0.25%)
occurrences causally related to treatment / all	2 / 6	0 / 5	1 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis acute			
subjects affected / exposed	5 / 2798 (0.18%)	4 / 3275 (0.12%)	2 / 2780 (0.07%)
occurrences causally related to treatment / all	3 / 5	1 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Cholecystitis chronic			
subjects affected / exposed	1 / 2798 (0.04%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	3 / 2798 (0.11%)	7 / 3275 (0.21%)	2 / 2780 (0.07%)
occurrences causally related to treatment / all	2 / 3	2 / 7	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholestasis			
subjects affected / exposed	1 / 2798 (0.04%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	2 / 2	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic cirrhosis			

subjects affected / exposed	0 / 2798 (0.00%)	2 / 3275 (0.06%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Hepatic cyst			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis			
subjects affected / exposed	2 / 2798 (0.07%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis fulminant			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatomegaly			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaundice cholestatic			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Liver disorder			

subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Portal hypertension			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Investigations			
Angiogram			
subjects affected / exposed	1 / 2798 (0.04%)	1 / 3275 (0.03%)	3 / 2780 (0.11%)
occurrences causally related to treatment / all	0 / 1	0 / 1	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arteriogram coronary			
subjects affected / exposed	1 / 2798 (0.04%)	1 / 3275 (0.03%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthroscopy			
subjects affected / exposed	0 / 2798 (0.00%)	2 / 3275 (0.06%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatinine increased			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood magnesium decreased			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colonoscopy			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystoscopy			

subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ecg signs of myocardial ischaemia			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ejection fraction decreased			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoglobin decreased			
subjects affected / exposed	0 / 2798 (0.00%)	2 / 3275 (0.06%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Heart rate abnormal			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Heart rate irregular			
subjects affected / exposed	1 / 2798 (0.04%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic enzyme increased			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver function test abnormal			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	2 / 2780 (0.07%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver function test increased			

subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Platelet count decreased			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatic specific antigen increased			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Red blood cell sedimentation rate increased			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Weight decreased			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Abdominal wound dehiscence			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Accidental overdose			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Animal bite			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ankle fracture			

subjects affected / exposed	1 / 2798 (0.04%)	3 / 3275 (0.09%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic injury			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Brain contusion			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral haemorrhage traumatic			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical vertebral fracture			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest injury			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Concussion			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Confusion postoperative			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Contusion			

subjects affected / exposed	2 / 2798 (0.07%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	1 / 2	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Craniocerebral injury			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug toxicity			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eschar			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial bones fracture			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	4 / 2798 (0.14%)	13 / 3275 (0.40%)	7 / 2780 (0.25%)
occurrences causally related to treatment / all	3 / 4	2 / 15	2 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femoral neck fracture			
subjects affected / exposed	2 / 2798 (0.07%)	8 / 3275 (0.24%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	1 / 2	3 / 8	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	5 / 2798 (0.18%)	11 / 3275 (0.34%)	7 / 2780 (0.25%)
occurrences causally related to treatment / all	1 / 5	2 / 12	1 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fibula fracture			

subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foot fracture			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fractured sacrum			
subjects affected / exposed	0 / 2798 (0.00%)	2 / 3275 (0.06%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hand fracture			
subjects affected / exposed	2 / 2798 (0.07%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head injury			
subjects affected / exposed	0 / 2798 (0.00%)	2 / 3275 (0.06%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip fracture			
subjects affected / exposed	5 / 2798 (0.18%)	12 / 3275 (0.37%)	7 / 2780 (0.25%)
occurrences causally related to treatment / all	0 / 5	0 / 12	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Humerus fracture			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	2 / 2780 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
In-Stent arterial restenosis			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
In-Stent coronary artery restenosis			

subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incarcerated incisional hernia			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incisional hernia			
subjects affected / exposed	1 / 2798 (0.04%)	3 / 3275 (0.09%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury			
subjects affected / exposed	1 / 2798 (0.04%)	1 / 3275 (0.03%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Jaw fracture			
subjects affected / exposed	1 / 2798 (0.04%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint dislocation			
subjects affected / exposed	1 / 2798 (0.04%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laceration			
subjects affected / exposed	0 / 2798 (0.00%)	3 / 3275 (0.09%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ligament sprain			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Limb traumatic amputation			

subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower limb fracture			
subjects affected / exposed	1 / 2798 (0.04%)	1 / 3275 (0.03%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar vertebral fracture			
subjects affected / exposed	1 / 2798 (0.04%)	8 / 3275 (0.24%)	2 / 2780 (0.07%)
occurrences causally related to treatment / all	0 / 1	2 / 8	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meniscus injury			
subjects affected / exposed	0 / 2798 (0.00%)	2 / 3275 (0.06%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meniscus lesion			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple fractures			
subjects affected / exposed	2 / 2798 (0.07%)	2 / 3275 (0.06%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple injuries			
subjects affected / exposed	1 / 2798 (0.04%)	2 / 3275 (0.06%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Muscle rupture			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle strain			

subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Overdose			
subjects affected / exposed	3 / 2798 (0.11%)	3 / 3275 (0.09%)	5 / 2780 (0.18%)
occurrences causally related to treatment / all	2 / 4	0 / 3	2 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Patella fracture			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic fracture			
subjects affected / exposed	0 / 2798 (0.00%)	2 / 3275 (0.06%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periorbital haematoma			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural bile leak			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural diarrhoea			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural fistula			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural haematoma			

subjects affected / exposed	1 / 2798 (0.04%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural haematuria			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural haemorrhage			
subjects affected / exposed	0 / 2798 (0.00%)	2 / 3275 (0.06%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural haemorrhage			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural pain			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pubis fracture			
subjects affected / exposed	2 / 2798 (0.07%)	2 / 3275 (0.06%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	1 / 2	1 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radius fracture			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib fracture			
subjects affected / exposed	1 / 2798 (0.04%)	2 / 3275 (0.06%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road traffic accident			

subjects affected / exposed	1 / 2798 (0.04%)	1 / 3275 (0.03%)	2 / 2780 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Scapula fracture			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skull fracture			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Spinal column injury			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal compression fracture			
subjects affected / exposed	0 / 2798 (0.00%)	2 / 3275 (0.06%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal fracture			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stomal hernia			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subarachnoid haemorrhage			
subjects affected / exposed	0 / 2798 (0.00%)	2 / 3275 (0.06%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			

subjects affected / exposed	4 / 2798 (0.14%)	5 / 3275 (0.15%)	4 / 2780 (0.14%)
occurrences causally related to treatment / all	3 / 5	4 / 5	2 / 4
deaths causally related to treatment / all	1 / 1	1 / 1	1 / 1
Tendon rupture			
subjects affected / exposed	0 / 2798 (0.00%)	2 / 3275 (0.06%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Therapeutic agent toxicity			
subjects affected / exposed	3 / 2798 (0.11%)	0 / 3275 (0.00%)	2 / 2780 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thoracic vertebral fracture			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tibia fracture			
subjects affected / exposed	0 / 2798 (0.00%)	3 / 3275 (0.09%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxicity to various agents			
subjects affected / exposed	0 / 2798 (0.00%)	5 / 3275 (0.15%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Traumatic brain injury			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	2 / 2780 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Traumatic haematoma			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	2 / 2780 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Traumatic haemorrhage			

subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ulna fracture			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	2 / 2780 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper limb fracture			
subjects affected / exposed	0 / 2798 (0.00%)	4 / 3275 (0.12%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound evisceration			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound secretion			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wrist fracture			
subjects affected / exposed	0 / 2798 (0.00%)	2 / 3275 (0.06%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Atrial septal defect			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	2 / 2780 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital cystic kidney disease			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal arteriovenous malformation			

subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liddle's syndrome			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	3 / 2798 (0.11%)	7 / 3275 (0.21%)	6 / 2780 (0.22%)
occurrences causally related to treatment / all	1 / 3	2 / 7	2 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute left ventricular failure			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Acute myocardial infarction			
subjects affected / exposed	13 / 2798 (0.46%)	25 / 3275 (0.76%)	19 / 2780 (0.68%)
occurrences causally related to treatment / all	3 / 13	11 / 27	6 / 21
deaths causally related to treatment / all	1 / 3	2 / 6	2 / 5
Angina pectoris			
subjects affected / exposed	5 / 2798 (0.18%)	15 / 3275 (0.46%)	9 / 2780 (0.32%)
occurrences causally related to treatment / all	0 / 5	4 / 15	2 / 10
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina unstable			
subjects affected / exposed	21 / 2798 (0.75%)	17 / 3275 (0.52%)	12 / 2780 (0.43%)
occurrences causally related to treatment / all	9 / 23	4 / 17	6 / 13
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Aortic valve incompetence			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic valve stenosis			

subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arrhythmia			
subjects affected / exposed	0 / 2798 (0.00%)	4 / 3275 (0.12%)	2 / 2780 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 3	0 / 1
Arrhythmia supraventricular			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	2 / 2780 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arteriosclerosis coronary artery			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	77 / 2798 (2.75%)	114 / 3275 (3.48%)	71 / 2780 (2.55%)
occurrences causally related to treatment / all	17 / 89	37 / 169	24 / 94
deaths causally related to treatment / all	1 / 1	0 / 2	1 / 1
Atrial flutter			
subjects affected / exposed	7 / 2798 (0.25%)	8 / 3275 (0.24%)	6 / 2780 (0.22%)
occurrences causally related to treatment / all	4 / 8	3 / 8	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial tachycardia			
subjects affected / exposed	2 / 2798 (0.07%)	2 / 3275 (0.06%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 2	2 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block			
subjects affected / exposed	1 / 2798 (0.04%)	3 / 3275 (0.09%)	2 / 2780 (0.07%)
occurrences causally related to treatment / all	0 / 1	1 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block complete			

subjects affected / exposed	3 / 2798 (0.11%)	1 / 3275 (0.03%)	2 / 2780 (0.07%)
occurrences causally related to treatment / all	1 / 3	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bradyarrhythmia			
subjects affected / exposed	2 / 2798 (0.07%)	3 / 3275 (0.09%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bradycardia			
subjects affected / exposed	6 / 2798 (0.21%)	11 / 3275 (0.34%)	5 / 2780 (0.18%)
occurrences causally related to treatment / all	1 / 6	1 / 11	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	4 / 2798 (0.14%)	12 / 3275 (0.37%)	9 / 2780 (0.32%)
occurrences causally related to treatment / all	1 / 4	0 / 12	4 / 9
deaths causally related to treatment / all	1 / 2	0 / 8	3 / 7
Cardiac asthma			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorder			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	70 / 2798 (2.50%)	120 / 3275 (3.66%)	79 / 2780 (2.84%)
occurrences causally related to treatment / all	11 / 84	31 / 179	23 / 95
deaths causally related to treatment / all	0 / 4	2 / 13	1 / 3
Cardiac failure acute			
subjects affected / exposed	3 / 2798 (0.11%)	3 / 3275 (0.09%)	7 / 2780 (0.25%)
occurrences causally related to treatment / all	0 / 3	1 / 3	1 / 8
deaths causally related to treatment / all	0 / 0	1 / 3	0 / 0
Cardiac failure chronic			

subjects affected / exposed	0 / 2798 (0.00%)	7 / 3275 (0.21%)	4 / 2780 (0.14%)
occurrences causally related to treatment / all	0 / 0	2 / 7	2 / 4
deaths causally related to treatment / all	0 / 0	0 / 1	1 / 2
Cardiac failure congestive			
subjects affected / exposed	46 / 2798 (1.64%)	55 / 3275 (1.68%)	36 / 2780 (1.29%)
occurrences causally related to treatment / all	17 / 66	26 / 73	9 / 42
deaths causally related to treatment / all	1 / 5	3 / 8	0 / 0
Cardio-Respiratory arrest			
subjects affected / exposed	2 / 2798 (0.07%)	9 / 3275 (0.27%)	2 / 2780 (0.07%)
occurrences causally related to treatment / all	0 / 2	2 / 9	0 / 2
deaths causally related to treatment / all	0 / 2	2 / 7	0 / 2
Cardiogenic shock			
subjects affected / exposed	1 / 2798 (0.04%)	5 / 3275 (0.15%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 5	0 / 0
deaths causally related to treatment / all	0 / 1	1 / 3	0 / 0
Cardiomyopathy			
subjects affected / exposed	1 / 2798 (0.04%)	1 / 3275 (0.03%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiopulmonary failure			
subjects affected / exposed	3 / 2798 (0.11%)	5 / 3275 (0.15%)	3 / 2780 (0.11%)
occurrences causally related to treatment / all	0 / 3	0 / 6	1 / 3
deaths causally related to treatment / all	0 / 1	0 / 4	0 / 2
Cardiovascular insufficiency			
subjects affected / exposed	1 / 2798 (0.04%)	1 / 3275 (0.03%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Carditis			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Conduction disorder			

subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congestive cardiomyopathy			
subjects affected / exposed	0 / 2798 (0.00%)	3 / 3275 (0.09%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 2	0 / 0
Cor pulmonale			
subjects affected / exposed	1 / 2798 (0.04%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Coronary artery disease			
subjects affected / exposed	4 / 2798 (0.14%)	16 / 3275 (0.49%)	7 / 2780 (0.25%)
occurrences causally related to treatment / all	0 / 5	9 / 18	2 / 8
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 1
Coronary artery insufficiency			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Coronary artery occlusion			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery stenosis			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Defect conduction intraventricular			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Heart valve incompetence			

subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive heart disease			
subjects affected / exposed	0 / 2798 (0.00%)	2 / 3275 (0.06%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intracardiac thrombus			
subjects affected / exposed	3 / 2798 (0.11%)	0 / 3275 (0.00%)	3 / 2780 (0.11%)
occurrences causally related to treatment / all	1 / 3	0 / 0	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic cardiomyopathy			
subjects affected / exposed	1 / 2798 (0.04%)	3 / 3275 (0.09%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 3	0 / 0
Left ventricular dysfunction			
subjects affected / exposed	0 / 2798 (0.00%)	3 / 3275 (0.09%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Left ventricular failure			
subjects affected / exposed	0 / 2798 (0.00%)	7 / 3275 (0.21%)	3 / 2780 (0.11%)
occurrences causally related to treatment / all	0 / 0	4 / 7	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Microvascular angina			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mitral valve disease			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mitral valve incompetence			

subjects affected / exposed	1 / 2798 (0.04%)	5 / 3275 (0.15%)	3 / 2780 (0.11%)
occurrences causally related to treatment / all	0 / 1	2 / 6	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mitral valve prolapse			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mitral valve stenosis			
subjects affected / exposed	0 / 2798 (0.00%)	4 / 3275 (0.12%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	14 / 2798 (0.50%)	25 / 3275 (0.76%)	14 / 2780 (0.50%)
occurrences causally related to treatment / all	4 / 14	5 / 25	6 / 14
deaths causally related to treatment / all	1 / 4	0 / 8	2 / 3
Myocardial ischaemia			
subjects affected / exposed	3 / 2798 (0.11%)	4 / 3275 (0.12%)	2 / 2780 (0.07%)
occurrences causally related to treatment / all	1 / 3	0 / 4	1 / 3
deaths causally related to treatment / all	1 / 1	0 / 1	0 / 0
Nodal arrhythmia			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nodal rhythm			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Palpitations			
subjects affected / exposed	4 / 2798 (0.14%)	2 / 3275 (0.06%)	2 / 2780 (0.07%)
occurrences causally related to treatment / all	3 / 5	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			

subjects affected / exposed	0 / 2798 (0.00%)	2 / 3275 (0.06%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	1 / 2	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis constrictive			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleuropericarditis			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prinzmetal angina			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rheumatic heart disease			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Right ventricular failure			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sick sinus syndrome			
subjects affected / exposed	9 / 2798 (0.32%)	0 / 3275 (0.00%)	14 / 2780 (0.50%)
occurrences causally related to treatment / all	1 / 10	0 / 0	1 / 14
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinoatrial block			

subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus arrest			
subjects affected / exposed	0 / 2798 (0.00%)	2 / 3275 (0.06%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus arrhythmia			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus bradycardia			
subjects affected / exposed	1 / 2798 (0.04%)	1 / 3275 (0.03%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus node dysfunction			
subjects affected / exposed	0 / 2798 (0.00%)	18 / 3275 (0.55%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	4 / 19	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	3 / 2798 (0.11%)	1 / 3275 (0.03%)	6 / 2780 (0.22%)
occurrences causally related to treatment / all	3 / 5	0 / 1	1 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachyarrhythmia			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			
subjects affected / exposed	2 / 2798 (0.07%)	2 / 3275 (0.06%)	2 / 2780 (0.07%)
occurrences causally related to treatment / all	1 / 2	1 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tricuspid valve incompetence			

subjects affected / exposed	1 / 2798 (0.04%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular arrhythmia			
subjects affected / exposed	1 / 2798 (0.04%)	4 / 3275 (0.12%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Ventricular extrasystoles			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular failure			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Ventricular fibrillation			
subjects affected / exposed	1 / 2798 (0.04%)	3 / 3275 (0.09%)	2 / 2780 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 1
Ventricular tachycardia			
subjects affected / exposed	3 / 2798 (0.11%)	4 / 3275 (0.12%)	3 / 2780 (0.11%)
occurrences causally related to treatment / all	1 / 4	0 / 4	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Nervous system disorders			
Altered state of consciousness			
subjects affected / exposed	0 / 2798 (0.00%)	2 / 3275 (0.06%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Aphasia			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Autonomic nervous system imbalance			

subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Balance disorder			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Basal ganglia haemorrhage			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain stem haemorrhage			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Brain stem infarction			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid arterial embolus			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid artery stenosis			
subjects affected / exposed	0 / 2798 (0.00%)	4 / 3275 (0.12%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	3 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carpal tunnel syndrome			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebellar ataxia			

subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebellar infarction			
subjects affected / exposed	0 / 2798 (0.00%)	2 / 3275 (0.06%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral artery embolism			
subjects affected / exposed	0 / 2798 (0.00%)	2 / 3275 (0.06%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral cyst			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral haematoma			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral haemorrhage			
subjects affected / exposed	3 / 2798 (0.11%)	10 / 3275 (0.31%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	3 / 3	8 / 10	1 / 1
deaths causally related to treatment / all	2 / 2	1 / 3	1 / 1
Cerebral infarction			
subjects affected / exposed	2 / 2798 (0.07%)	10 / 3275 (0.31%)	7 / 2780 (0.25%)
occurrences causally related to treatment / all	0 / 2	7 / 12	2 / 7
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Cerebral microhaemorrhage			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral thrombosis			

subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	17 / 2798 (0.61%)	16 / 3275 (0.49%)	44 / 2780 (1.58%)
occurrences causally related to treatment / all	6 / 17	4 / 19	14 / 45
deaths causally related to treatment / all	2 / 4	0 / 3	0 / 2
Cerebrovascular disorder			
subjects affected / exposed	0 / 2798 (0.00%)	2 / 3275 (0.06%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular insufficiency			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical root pain			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cognitive disorder			
subjects affected / exposed	0 / 2798 (0.00%)	2 / 3275 (0.06%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Coma			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Convulsion			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	2 / 2780 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cubital tunnel syndrome			

subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dementia			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dementia alzheimer's type			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Dementia with lewy bodies			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depressed level of consciousness			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Diabetic hyperglycaemic coma			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic neuropathy			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			
subjects affected / exposed	1 / 2798 (0.04%)	6 / 3275 (0.18%)	10 / 2780 (0.36%)
occurrences causally related to treatment / all	0 / 1	2 / 6	4 / 10
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysarthria			

subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyskinesia			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolic stroke			
subjects affected / exposed	0 / 2798 (0.00%)	3 / 3275 (0.09%)	2 / 2780 (0.07%)
occurrences causally related to treatment / all	0 / 0	2 / 3	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Encephalopathy			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epilepsy			
subjects affected / exposed	4 / 2798 (0.14%)	4 / 3275 (0.12%)	2 / 2780 (0.07%)
occurrences causally related to treatment / all	1 / 4	2 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	1 / 2798 (0.04%)	2 / 3275 (0.06%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhagic cerebral infarction			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhagic stroke			
subjects affected / exposed	5 / 2798 (0.18%)	8 / 3275 (0.24%)	8 / 2780 (0.29%)
occurrences causally related to treatment / all	4 / 5	7 / 8	6 / 8
deaths causally related to treatment / all	0 / 1	3 / 4	0 / 0
Headache			

subjects affected / exposed	1 / 2798 (0.04%)	2 / 3275 (0.06%)	2 / 2780 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiparesis			
subjects affected / exposed	2 / 2798 (0.07%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydrocephalus			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoaesthesia			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemic coma			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemic encephalopathy			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intraventricular haemorrhage			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic cerebral infarction			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic stroke			

subjects affected / exposed	24 / 2798 (0.86%)	26 / 3275 (0.79%)	51 / 2780 (1.83%)
occurrences causally related to treatment / all	11 / 27	7 / 27	27 / 55
deaths causally related to treatment / all	0 / 1	0 / 1	1 / 3
Lacunar infarction			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lethargy			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Loss of consciousness			
subjects affected / exposed	0 / 2798 (0.00%)	2 / 3275 (0.06%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar radiculopathy			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic encephalopathy			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	2 / 2780 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Migraine			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myoclonus			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuritis			

subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuroglycopenia			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuropathy peripheral			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraesthesia			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraplegia			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parkinson's disease			
subjects affected / exposed	0 / 2798 (0.00%)	4 / 3275 (0.12%)	4 / 2780 (0.14%)
occurrences causally related to treatment / all	0 / 0	4 / 7	2 / 5
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Partial seizures			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral nerve palsy			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post-Traumatic epilepsy			

subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Presyncope			
subjects affected / exposed	5 / 2798 (0.18%)	4 / 3275 (0.12%)	2 / 2780 (0.07%)
occurrences causally related to treatment / all	1 / 5	1 / 4	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sciatica			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 2798 (0.00%)	3 / 3275 (0.09%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	3 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Simple partial seizures			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Status epilepticus			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subarachnoid haemorrhage			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	2 / 2780 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Subdural effusion			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			

subjects affected / exposed	8 / 2798 (0.29%)	26 / 3275 (0.79%)	21 / 2780 (0.76%)
occurrences causally related to treatment / all	2 / 8	4 / 27	4 / 22
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombotic stroke			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	10 / 2798 (0.36%)	13 / 3275 (0.40%)	30 / 2780 (1.08%)
occurrences causally related to treatment / all	3 / 10	3 / 13	14 / 33
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tremor			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uraemic encephalopathy			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular dementia			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular encephalopathy			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertebrobasilar insufficiency			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viith nerve paralysis			

subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	12 / 2798 (0.43%)	24 / 3275 (0.73%)	11 / 2780 (0.40%)
occurrences causally related to treatment / all	11 / 18	18 / 26	7 / 11
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia megaloblastic			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aplastic anaemia			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Coagulopathy			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemolytic anaemia			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhagic diathesis			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Iron deficiency anaemia			
subjects affected / exposed	1 / 2798 (0.04%)	3 / 3275 (0.09%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 2	2 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukocytosis			

subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukopenia			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphadenopathy			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	1 / 2798 (0.04%)	1 / 3275 (0.03%)	2 / 2780 (0.07%)
occurrences causally related to treatment / all	1 / 1	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Ear disorder			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear haemorrhage			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertigo			
subjects affected / exposed	2 / 2798 (0.07%)	5 / 3275 (0.15%)	3 / 2780 (0.11%)
occurrences causally related to treatment / all	1 / 2	1 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertigo positional			

subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Amaurosis fugax			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cataract			
subjects affected / exposed	2 / 2798 (0.07%)	6 / 3275 (0.18%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 2	1 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diplopia			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye haemorrhage			
subjects affected / exposed	2 / 2798 (0.07%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye pain			
subjects affected / exposed	0 / 2798 (0.00%)	2 / 3275 (0.06%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eyelid ptosis			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Keratitis			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal artery embolism			

subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal artery occlusion			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal detachment			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	2 / 2780 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tolosa-Hunt syndrome			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vitreous haemorrhage			
subjects affected / exposed	2 / 2798 (0.07%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal adhesions			
subjects affected / exposed	1 / 2798 (0.04%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal distension			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal hernia			
subjects affected / exposed	0 / 2798 (0.00%)	2 / 3275 (0.06%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal mass			

subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	5 / 2798 (0.18%)	6 / 3275 (0.18%)	5 / 2780 (0.18%)
occurrences causally related to treatment / all	3 / 6	1 / 6	2 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal strangulated hernia			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal wall haematoma			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute abdomen			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal fistula			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 2798 (0.00%)	3 / 3275 (0.09%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Barrett's oesophagus			

subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic gastritis			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	2 / 2798 (0.07%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis ulcerative			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colonic polyp			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	1 / 2798 (0.04%)	6 / 3275 (0.18%)	2 / 2780 (0.07%)
occurrences causally related to treatment / all	0 / 1	1 / 7	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 2798 (0.00%)	11 / 3275 (0.34%)	5 / 2780 (0.18%)
occurrences causally related to treatment / all	0 / 0	3 / 11	2 / 5
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Diverticulum			
subjects affected / exposed	0 / 2798 (0.00%)	2 / 3275 (0.06%)	2 / 2780 (0.07%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum intestinal			

subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal ulcer			
subjects affected / exposed	1 / 2798 (0.04%)	3 / 3275 (0.09%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 1	2 / 3	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal ulcer haemorrhage			
subjects affected / exposed	2 / 2798 (0.07%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	2 / 2	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal ulcer perforation			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Duodenitis			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspepsia			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	2 / 2780 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	1 / 2798 (0.04%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Faecaloma			
subjects affected / exposed	1 / 2798 (0.04%)	2 / 3275 (0.06%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Food poisoning			

subjects affected / exposed	0 / 2798 (0.00%)	2 / 3275 (0.06%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric disorder			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric haemorrhage			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Gastric ulcer			
subjects affected / exposed	1 / 2798 (0.04%)	4 / 3275 (0.12%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	1 / 1	3 / 4	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric ulcer haemorrhage			
subjects affected / exposed	1 / 2798 (0.04%)	2 / 3275 (0.06%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	5 / 2798 (0.18%)	3 / 3275 (0.09%)	6 / 2780 (0.22%)
occurrences causally related to treatment / all	2 / 5	0 / 3	3 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis erosive			
subjects affected / exposed	1 / 2798 (0.04%)	2 / 3275 (0.06%)	2 / 2780 (0.07%)
occurrences causally related to treatment / all	1 / 1	2 / 2	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis haemorrhagic			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroduodenitis			

subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorder			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	4 / 2798 (0.14%)	20 / 3275 (0.61%)	11 / 2780 (0.40%)
occurrences causally related to treatment / all	3 / 4	19 / 20	7 / 11
deaths causally related to treatment / all	2 / 2	1 / 1	1 / 1
Gastrointestinal hypomotility			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal perforation			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gingival bleeding			
subjects affected / exposed	2 / 2798 (0.07%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	2 / 3	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematemesis			
subjects affected / exposed	1 / 2798 (0.04%)	4 / 3275 (0.12%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	1 / 1	1 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Haematochezia			

subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 2798 (0.00%)	3 / 3275 (0.09%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhoids			
subjects affected / exposed	0 / 2798 (0.00%)	3 / 3275 (0.09%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	3 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hiatus hernia			
subjects affected / exposed	1 / 2798 (0.04%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus paralytic			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incarcerated umbilical hernia			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia			
subjects affected / exposed	3 / 2798 (0.11%)	12 / 3275 (0.37%)	6 / 2780 (0.22%)
occurrences causally related to treatment / all	0 / 3	2 / 12	1 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia strangulated			

subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal haemorrhage			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal ischaemia			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	2 / 2780 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	1 / 2798 (0.04%)	6 / 3275 (0.18%)	2 / 2780 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 6	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal ulcer			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal obstruction			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine perforation			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine polyp			
subjects affected / exposed	0 / 2798 (0.00%)	3 / 3275 (0.09%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower gastrointestinal haemorrhage			

subjects affected / exposed	0 / 2798 (0.00%)	2 / 3275 (0.06%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar hernia			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mallory-Weiss syndrome			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melaena			
subjects affected / exposed	5 / 2798 (0.18%)	5 / 3275 (0.15%)	2 / 2780 (0.07%)
occurrences causally related to treatment / all	5 / 5	6 / 6	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mesenteric artery embolism			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mesenteric artery thrombosis			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mouth haemorrhage			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	1 / 2798 (0.04%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal achalasia			

subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal dilatation			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal stenosis			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal varices haemorrhage			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	2 / 2798 (0.07%)	2 / 3275 (0.06%)	3 / 2780 (0.11%)
occurrences causally related to treatment / all	1 / 2	0 / 2	3 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis acute			
subjects affected / exposed	1 / 2798 (0.04%)	3 / 3275 (0.09%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 1	2 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis chronic			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peptic ulcer			

subjects affected / exposed	1 / 2798 (0.04%)	1 / 3275 (0.03%)	2 / 2780 (0.07%)
occurrences causally related to treatment / all	1 / 1	0 / 1	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Proctitis			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Proctitis ulcerative			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	8 / 2798 (0.29%)	8 / 3275 (0.24%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	7 / 10	8 / 8	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reflux oesophagitis			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retroperitoneal haematoma			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	1 / 2798 (0.04%)	2 / 3275 (0.06%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spigelian hernia			

subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Splenic artery aneurysm			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subileus			
subjects affected / exposed	2 / 2798 (0.07%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tooth loss			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical hernia			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 2798 (0.00%)	15 / 3275 (0.46%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	12 / 16	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Volvulus			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	2 / 2798 (0.07%)	2 / 3275 (0.06%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	1 / 2	3 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Angioedema			

subjects affected / exposed	1 / 2798 (0.04%)	2 / 3275 (0.06%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 1	2 / 2	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood blister			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Decubitus ulcer			
subjects affected / exposed	2 / 2798 (0.07%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermatitis			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermatitis herpetiformis			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic foot			
subjects affected / exposed	0 / 2798 (0.00%)	3 / 3275 (0.09%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erythema			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Purpura			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash erythematous			

subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	2 / 2	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin lesion			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin ulcer			
subjects affected / exposed	0 / 2798 (0.00%)	3 / 3275 (0.09%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 2798 (0.00%)	25 / 3275 (0.76%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	8 / 28	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 2	0 / 0
Azotaemia			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder mass			
subjects affected / exposed	2 / 2798 (0.07%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus bladder			
subjects affected / exposed	0 / 2798 (0.00%)	2 / 3275 (0.06%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus ureteric			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	2 / 2780 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus urethral			

subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus urinary			
subjects affected / exposed	3 / 2798 (0.11%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic kidney disease			
subjects affected / exposed	0 / 2798 (0.00%)	3 / 3275 (0.09%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Cystitis haemorrhagic			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic nephropathy			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysuria			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	5 / 2798 (0.18%)	13 / 3275 (0.40%)	6 / 2780 (0.22%)
occurrences causally related to treatment / all	6 / 6	9 / 14	3 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage urinary tract			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive nephropathy			

subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			
subjects affected / exposed	1 / 2798 (0.04%)	2 / 3275 (0.06%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postrenal failure			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal colic			
subjects affected / exposed	1 / 2798 (0.04%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal cyst			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			
subjects affected / exposed	1 / 2798 (0.04%)	7 / 3275 (0.21%)	7 / 2780 (0.25%)
occurrences causally related to treatment / all	0 / 1	2 / 7	2 / 7
deaths causally related to treatment / all	0 / 0	0 / 1	1 / 1
Renal failure acute			
subjects affected / exposed	9 / 2798 (0.32%)	0 / 3275 (0.00%)	10 / 2780 (0.36%)
occurrences causally related to treatment / all	7 / 12	0 / 0	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure chronic			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal haemorrhage			

subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal impairment			
subjects affected / exposed	0 / 2798 (0.00%)	2 / 3275 (0.06%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	1 / 2	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal infarct			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal tubular necrosis			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urethral disorder			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary incontinence			
subjects affected / exposed	2 / 2798 (0.07%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention			
subjects affected / exposed	3 / 2798 (0.11%)	2 / 3275 (0.06%)	2 / 2780 (0.07%)
occurrences causally related to treatment / all	1 / 3	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Goitre			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperparathyroidism			

subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperthyroidism			
subjects affected / exposed	1 / 2798 (0.04%)	4 / 3275 (0.12%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypothyroidism			
subjects affected / exposed	1 / 2798 (0.04%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thyroid haemorrhage			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thyroid mass			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 2798 (0.04%)	2 / 3275 (0.06%)	2 / 2780 (0.07%)
occurrences causally related to treatment / all	0 / 1	1 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis			
subjects affected / exposed	0 / 2798 (0.00%)	2 / 3275 (0.06%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	7 / 2798 (0.25%)	9 / 3275 (0.27%)	4 / 2780 (0.14%)
occurrences causally related to treatment / all	2 / 7	0 / 9	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bursitis			

subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gouty arthritis			
subjects affected / exposed	1 / 2798 (0.04%)	2 / 3275 (0.06%)	2 / 2780 (0.07%)
occurrences causally related to treatment / all	1 / 1	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemarthrosis			
subjects affected / exposed	1 / 2798 (0.04%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal mass			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc degeneration			
subjects affected / exposed	0 / 2798 (0.00%)	2 / 3275 (0.06%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc protrusion			
subjects affected / exposed	1 / 2798 (0.04%)	4 / 3275 (0.12%)	4 / 2780 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 5	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint swelling			
subjects affected / exposed	1 / 2798 (0.04%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar spinal stenosis			
subjects affected / exposed	0 / 2798 (0.00%)	4 / 3275 (0.12%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	1 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle haemorrhage			

subjects affected / exposed	1 / 2798 (0.04%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Muscle spasms			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			
subjects affected / exposed	0 / 2798 (0.00%)	2 / 3275 (0.06%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal chest pain			
subjects affected / exposed	1 / 2798 (0.04%)	3 / 3275 (0.09%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal pain			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal stiffness			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myalgia			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myopathy			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			

subjects affected / exposed	11 / 2798 (0.39%)	19 / 3275 (0.58%)	3 / 2780 (0.11%)
occurrences causally related to treatment / all	1 / 11	4 / 20	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteochondrosis			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteopenia			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			
subjects affected / exposed	2 / 2798 (0.07%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Plantar fasciitis			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polyarthritis			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polymyalgia rheumatica			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhabdomyolysis			
subjects affected / exposed	0 / 2798 (0.00%)	3 / 3275 (0.09%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rheumatoid arthritis			

subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotator cuff syndrome			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	2 / 2780 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal column stenosis			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal osteoarthritis			
subjects affected / exposed	1 / 2798 (0.04%)	4 / 3275 (0.12%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal pain			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic lupus erythematosus			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendon pain			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abdominal wall abscess			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal wall infection			

subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess limb			
subjects affected / exposed	0 / 2798 (0.00%)	2 / 3275 (0.06%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Amoebic dysentery			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	0 / 2798 (0.00%)	6 / 3275 (0.18%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	1 / 6	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Arthritis bacterial			
subjects affected / exposed	2 / 2798 (0.07%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiectasis			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	7 / 2798 (0.25%)	15 / 3275 (0.46%)	7 / 2780 (0.25%)
occurrences causally related to treatment / all	1 / 7	3 / 16	2 / 7
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Bronchopneumonia			

subjects affected / exposed	3 / 2798 (0.11%)	0 / 3275 (0.00%)	5 / 2780 (0.18%)
occurrences causally related to treatment / all	1 / 3	0 / 0	3 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Cellulitis			
subjects affected / exposed	7 / 2798 (0.25%)	13 / 3275 (0.40%)	5 / 2780 (0.18%)
occurrences causally related to treatment / all	1 / 7	3 / 15	1 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic sinusitis			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium colitis			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile colitis			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	3 / 2780 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 1	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Colonic abscess			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			
subjects affected / exposed	0 / 2798 (0.00%)	2 / 3275 (0.06%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dengue fever			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic foot infection			

subjects affected / exposed	0 / 2798 (0.00%)	2 / 3275 (0.06%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated tuberculosis			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	0 / 2798 (0.00%)	7 / 3275 (0.21%)	3 / 2780 (0.11%)
occurrences causally related to treatment / all	0 / 0	1 / 8	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis intestinal haemorrhagic			
subjects affected / exposed	0 / 2798 (0.00%)	2 / 3275 (0.06%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Empyema			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Encephalitis viral			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocarditis			
subjects affected / exposed	1 / 2798 (0.04%)	3 / 3275 (0.09%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endophthalmitis			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erysipelas			

subjects affected / exposed	0 / 2798 (0.00%)	8 / 3275 (0.24%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 8	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia bacteraemia			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia infection			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gangrene			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	8 / 2798 (0.29%)	15 / 3275 (0.46%)	5 / 2780 (0.18%)
occurrences causally related to treatment / all	0 / 8	3 / 17	1 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis salmonella			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			
subjects affected / exposed	0 / 2798 (0.00%)	3 / 3275 (0.09%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal infection			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Groin infection			

subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Helicobacter gastritis			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Helicobacter infection			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic amoebiasis			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis c			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis e			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			
subjects affected / exposed	0 / 2798 (0.00%)	3 / 3275 (0.09%)	2 / 2780 (0.07%)
occurrences causally related to treatment / all	0 / 0	2 / 3	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Implant site infection			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			

subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infectious pleural effusion			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infective exacerbation of chronic obstructive airways disease			
subjects affected / exposed	1 / 2798 (0.04%)	1 / 3275 (0.03%)	2 / 2780 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Klebsiella bacteraemia			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Listeriosis			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver abscess			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lobar pneumonia			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Localised infection			

subjects affected / exposed	0 / 2798 (0.00%)	2 / 3275 (0.06%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	2 / 2798 (0.07%)	5 / 3275 (0.15%)	3 / 2780 (0.11%)
occurrences causally related to treatment / all	1 / 2	0 / 6	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
Lung infection			
subjects affected / exposed	0 / 2798 (0.00%)	2 / 3275 (0.06%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasopharyngitis			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nosocomial infection			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal candidiasis			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ophthalmic herpes zoster			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral candidiasis			

subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orchitis			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periorbital cellulitis			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	42 / 2798 (1.50%)	104 / 3275 (3.18%)	61 / 2780 (2.19%)
occurrences causally related to treatment / all	6 / 45	23 / 120	14 / 69
deaths causally related to treatment / all	1 / 5	2 / 8	0 / 2
Pneumonia escherichia			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia influenzal			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia klebsiella			

subjects affected / exposed	1 / 2798 (0.04%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia pneumococcal			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia primary atypical			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pneumonia streptococcal			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia viral			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	2 / 2780 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative abscess			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative wound infection			
subjects affected / exposed	1 / 2798 (0.04%)	2 / 3275 (0.06%)	2 / 2780 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate infection			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psoas abscess			

subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary sepsis			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary tuberculosis			
subjects affected / exposed	0 / 2798 (0.00%)	2 / 3275 (0.06%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Pyelonephritis			
subjects affected / exposed	1 / 2798 (0.04%)	2 / 3275 (0.06%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis acute			
subjects affected / exposed	1 / 2798 (0.04%)	1 / 3275 (0.03%)	2 / 2780 (0.07%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyometra			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	3 / 2798 (0.11%)	6 / 3275 (0.18%)	5 / 2780 (0.18%)
occurrences causally related to treatment / all	2 / 3	0 / 6	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	4 / 2798 (0.14%)	18 / 3275 (0.55%)	4 / 2780 (0.14%)
occurrences causally related to treatment / all	1 / 4	3 / 19	2 / 5
deaths causally related to treatment / all	0 / 0	2 / 5	0 / 0
Sepsis syndrome			

subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Septic shock			
subjects affected / exposed	4 / 2798 (0.14%)	14 / 3275 (0.43%)	2 / 2780 (0.07%)
occurrences causally related to treatment / all	1 / 4	2 / 14	0 / 2
deaths causally related to treatment / all	1 / 2	0 / 5	0 / 1
Sinusitis			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin infection			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue infection			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal infection			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal sepsis			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Tracheitis			

subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tracheobronchitis			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tuberculosis			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tuberculous pleurisy			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	3 / 2798 (0.11%)	3 / 3275 (0.09%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	13 / 2798 (0.46%)	24 / 3275 (0.73%)	16 / 2780 (0.58%)
occurrences causally related to treatment / all	1 / 14	3 / 26	3 / 16
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
Urinary tract infection bacterial			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection enterococcal			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			

subjects affected / exposed	1 / 2798 (0.04%)	4 / 3275 (0.12%)	2 / 2780 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 4	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vestibular neuronitis			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	3 / 2780 (0.11%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection			
subjects affected / exposed	2 / 2798 (0.07%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 2	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Cachexia			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	2 / 2780 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calciphylaxis			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Decreased appetite			
subjects affected / exposed	1 / 2798 (0.04%)	2 / 3275 (0.06%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	1 / 1	1 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			

subjects affected / exposed	9 / 2798 (0.32%)	11 / 3275 (0.34%)	7 / 2780 (0.25%)
occurrences causally related to treatment / all	1 / 9	1 / 13	1 / 7
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Diabetes mellitus			
subjects affected / exposed	5 / 2798 (0.18%)	7 / 3275 (0.21%)	4 / 2780 (0.14%)
occurrences causally related to treatment / all	1 / 5	2 / 7	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes mellitus inadequate control			
subjects affected / exposed	0 / 2798 (0.00%)	3 / 3275 (0.09%)	2 / 2780 (0.07%)
occurrences causally related to treatment / all	0 / 0	1 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes with hyperosmolarity			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrolyte imbalance			
subjects affected / exposed	1 / 2798 (0.04%)	2 / 3275 (0.06%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gout			
subjects affected / exposed	2 / 2798 (0.07%)	1 / 3275 (0.03%)	2 / 2780 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	3 / 2798 (0.11%)	2 / 3275 (0.06%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 4	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkalaemia			

subjects affected / exposed	0 / 2798 (0.00%)	5 / 3275 (0.15%)	3 / 2780 (0.11%)
occurrences causally related to treatment / all	0 / 0	2 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypernatraemia			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoalbuminaemia			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	8 / 2798 (0.29%)	12 / 3275 (0.37%)	3 / 2780 (0.11%)
occurrences causally related to treatment / all	2 / 10	3 / 15	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	0 / 2798 (0.00%)	2 / 3275 (0.06%)	3 / 2780 (0.11%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypomagnesaemia			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	4 / 2798 (0.14%)	6 / 3275 (0.18%)	4 / 2780 (0.14%)
occurrences causally related to treatment / all	5 / 7	2 / 6	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypophosphataemia			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypovolaemia			

subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lactic acidosis			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malnutrition			
subjects affected / exposed	0 / 2798 (0.00%)	0 / 3275 (0.00%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic acidosis			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obesity			
subjects affected / exposed	0 / 2798 (0.00%)	1 / 3275 (0.03%)	1 / 2780 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Starvation			
subjects affected / exposed	1 / 2798 (0.04%)	0 / 3275 (0.00%)	0 / 2780 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Type 2 diabetes mellitus			
subjects affected / exposed	1 / 2798 (0.04%)	2 / 3275 (0.06%)	2 / 2780 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	DB-Apixaban	OL-Apixaban	DB-ASA
Total subjects affected by non-serious adverse events			
subjects affected / exposed	208 / 2798 (7.43%)	276 / 3275 (8.43%)	274 / 2780 (9.86%)
Nervous system disorders			
Dizziness			
subjects affected / exposed	117 / 2798 (4.18%)	129 / 3275 (3.94%)	145 / 2780 (5.22%)
occurrences (all)	127	143	161
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	107 / 2798 (3.82%)	166 / 3275 (5.07%)	148 / 2780 (5.32%)
occurrences (all)	119	188	165

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
10 November 2008	To correct typographical errors in original protocol, to clarify protocol organization, language and definitions.
30 April 2010	Incorporates optional Long-Term Open-Label Extension (LTOLE)
02 November 2010	Changes applicable to LTOLE only: allows dose reduction, clarification to laboratory inclusion criteria and discontinuation of open-label apixaban
22 June 2011	Provides instructions to the Investigators if the result for the Serum Creatinine test fails to meet Exclusion Criteria at LTOLE entry or is above the alert high (AH) in the Clearstone lab report during ongoing therapy.
24 September 2013	Changes name of Medical Monitor and adds language regarding the Post Study Drug Access Program

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

On May 28, 2010, after a planned interim analysis for efficacy, the Data Monitoring Committee recommended early termination due to apixaban's superior efficacy over ASA, with an acceptable safety profile. The open-label phase is ongoing.

Notes: