



## Clinical trial results:

A multicenter, randomized, double-blind, parallel group, active-controlled study to evaluate the efficacy and safety of both aliskiren monotherapy and aliskiren/enalapril combination therapy compared to enalapril monotherapy, on morbidity and mortality in patients with chronic heart failure (NYHA Class II - IV).

The study is also known as Aliskiren Trial of Minimizing OutcomeS in Patients with HEart failure (ATMOSPHERE).

## Summary

EudraCT number	2008-004104-31
Trial protocol	AT DE SK NL FI SE DK LT BE PT IT IE ES CZ PL FR LV GB EE GR
Global end of trial date	05 October 2015

## Results information

Result version number	v1 (current)
This version publication date	20 October 2016
First version publication date	20 October 2016

## Trial information

### Trial identification

Sponsor protocol code	CSPP100F2301
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### Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00853658
WHO universal trial number (UTN)	-

Notes:

## Sponsors

Sponsor organisation name	Novartis Pharma AG
Sponsor organisation address	CH-4002, Basel, Switzerland,
Public contact	Clinical Disclosure Office, Novartis Pharma AG, 41 613241111,
Scientific contact	Clinical Disclosure Office, Novartis Pharma AG, 41 613241111,

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	05 October 2015
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	05 October 2015
Was the trial ended prematurely?	No

Notes:

## General information about the trial

Main objective of the trial:

The primary objectives of ATMOSPHERE were firstly to test whether the combination of aliskiren and enalapril is superior to enalapril monotherapy in delaying time to the first occurrence of CV death or HF hospitalization in patients with chronic heart failure (NYHA Class II-IV) and reduced ejection fraction, and secondly to test whether aliskiren monotherapy is superior, or at least non-inferior, to enalapril monotherapy using the same composite endpoint. The superiority comparison of the combination of aliskiren and enalapril versus enalapril monotherapy in patients without diabetes at baseline was added to the primary objectives through protocol amendment #4, in April 2013.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and the International Conference on Harmonization (ICH) Good Clinical Practice (GCP) guidelines. All the local regulatory requirements pertinent to safety of trial subjects were also followed during the conduct of the trial.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	13 March 2009
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

## Population of trial subjects

### Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 41
Country: Number of subjects enrolled	Austria: 59
Country: Number of subjects enrolled	Belgium: 73
Country: Number of subjects enrolled	Brazil: 201
Country: Number of subjects enrolled	Canada: 77
Country: Number of subjects enrolled	China: 465
Country: Number of subjects enrolled	Colombia: 145
Country: Number of subjects enrolled	Costa Rica: 17
Country: Number of subjects enrolled	Czech Republic: 307
Country: Number of subjects enrolled	Denmark: 253
Country: Number of subjects enrolled	Dominican Republic: 23
Country: Number of subjects enrolled	Argentina: 501
Country: Number of subjects enrolled	Estonia: 47
Country: Number of subjects enrolled	Finland: 24
Country: Number of subjects enrolled	France: 34
Country: Number of subjects enrolled	Germany: 469

Country: Number of subjects enrolled	United Kingdom: 48
Country: Number of subjects enrolled	Greece: 59
Country: Number of subjects enrolled	India: 782
Country: Number of subjects enrolled	Ireland: 16
Country: Number of subjects enrolled	Italy: 286
Country: Number of subjects enrolled	Japan: 210
Country: Number of subjects enrolled	Korea, Republic of: 143
Country: Number of subjects enrolled	Latvia: 65
Country: Number of subjects enrolled	Lithuania: 61
Country: Number of subjects enrolled	Mexico: 50
Country: Number of subjects enrolled	Netherlands: 162
Country: Number of subjects enrolled	Norway: 22
Country: Number of subjects enrolled	Peru: 116
Country: Number of subjects enrolled	Poland: 302
Country: Number of subjects enrolled	Portugal: 54
Country: Number of subjects enrolled	Romania: 290
Country: Number of subjects enrolled	Russian Federation: 554
Country: Number of subjects enrolled	Slovakia: 327
Country: Number of subjects enrolled	South Africa: 52
Country: Number of subjects enrolled	Spain: 142
Country: Number of subjects enrolled	Sweden: 141
Country: Number of subjects enrolled	Switzerland: 15
Country: Number of subjects enrolled	Taiwan: 113
Country: Number of subjects enrolled	Thailand: 56
Country: Number of subjects enrolled	Turkey: 70
Country: Number of subjects enrolled	United States: 116
Country: Number of subjects enrolled	Venezuela, Bolivarian Republic of: 76
Worldwide total number of subjects	7064
EEA total number of subjects	3241

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)	3605
From 65 to 84 years	3357
85 years and over	102

## Subject disposition

### Recruitment

Recruitment details: -

### Pre-assignment

Screening details:

During Active Run-in period, patients received enalapril for step 1 & 2 and then aliskiren on top of the max tolerated dose of enalapril for step 3. Patients who completed the run in were randomized in a 1:1:1 ratio to one of the 3 treatment arms (aliskiren/enalapril combination therapy, aliskiren monotherapy, or enalapril monotherapy).

### Period 1

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

### Arms

Are arms mutually exclusive?	Yes
<b>Arm title</b>	Combination Aliskiren / Enalapril

Arm description:

Aliskiren / Enalapril combination therapy-150 mg/10 mg titrated to 300 mg/ 10 mg film-coated tablets and administered orally.

Arm type	Experimental
Investigational medicinal product name	Aliskiren
Investigational medicinal product code	SPP100
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Aliskiren 150 mg titrated to 300 mg oral film-coated tablet daily.

Investigational medicinal product name	Enalapril
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Enalapril 10 mg oral film-coated tablet daily.

<b>Arm title</b>	Aliskiren
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Arm description:

Aliskiren monotherapy - 150 mg titrated to 300 mg film-coated tablets and administered orally.

Arm type	Experimental
Investigational medicinal product name	Aliskiren
Investigational medicinal product code	SPP100
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Aliskiren 150 mg titrated to 300 mg oral film-coated tablet daily.

<b>Arm title</b>	Enalapril
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Arm description:

Enalapril monotherapy -10 mg film-coated tablet and administered orally.

Arm type	Active comparator
Investigational medicinal product name	Enalapril
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Enalapril 10 mg oral film-coated tablet daily.

<b>Number of subjects in period 1</b>	Combination Aliskiren / Enalapril	Aliskiren	Enalapril
Started	2354	2356	2354
Full Analysis Set (FAS)	2340	2340	2336
Safety Set	2347	2348	2345
Completed	1567	1524	1539
Not completed	787	832	815
Vital Status known (alive) at study end	2	3	3
Death	713	768	753
H.A. Request	26	23	19
Vital Status at study end N/A	8	10	10
IRB request	-	-	2
Lost to follow-up	11	6	11
Vital Status unknown at study end	1	1	-
Patient's request	21	17	11
Missing study completion information	5	4	6

## Baseline characteristics

### Reporting groups

Reporting group title	Combination Aliskiren / Enalapril
Reporting group description: Aliskiren / Enalapril combination therapy-150 mg/10 mg titrated to 300 mg/ 10 mg film-coated tablets and administered orally.	
Reporting group title	Aliskiren
Reporting group description: Aliskiren monotherapy - 150 mg titrated to 300 mg film-coated tablets and administered orally.	
Reporting group title	Enalapril
Reporting group description: Enalapril monotherapy -10 mg film-coated tablet and administered orally.	

Reporting group values	Combination Aliskiren / Enalapril	Aliskiren	Enalapril
Number of subjects	2354	2356	2354
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	1219	1185	1201
From 65-84 years	1099	1130	1128
85 years and over	36	41	25
Age Continuous Units: years			
arithmetic mean	63.2	63.3	63.3
standard deviation	± 11.65	± 12.06	± 11.71
Gender, Male/Female Units: Subjects			
Male	1857	1822	1850
Female	497	534	504

Reporting group values	Total		
Number of subjects	7064		
Age categorical Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	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)	3605		
From 65-84 years	3357		
85 years and over	102		
Age Continuous			
Units: years			
arithmetic mean			
standard deviation	-		
Gender, Male/Female			
Units: Subjects			
Male	5529		
Female	1535		

## End points

### End points reporting groups

Reporting group title	Combination Aliskiren / Enalapril
Reporting group description: Aliskiren / Enalapril combination therapy-150 mg/10 mg titrated to 300 mg/ 10 mg film-coated tablets and administered orally.	
Reporting group title	Aliskiren
Reporting group description: Aliskiren monotherapy - 150 mg titrated to 300 mg film-coated tablets and administered orally.	
Reporting group title	Enalapril
Reporting group description: Enalapril monotherapy -10 mg film-coated tablet and administered orally.	

### Primary: Number of participants that had first occurrence of the composite endpoint, which is defined as either Cardiovascular (CV) death or Heart Failure (HF) hospitalization

End point title	Number of participants that had first occurrence of the composite endpoint, which is defined as either Cardiovascular (CV) death or Heart Failure (HF) hospitalization
End point description: Number of participants that had first occurrence of the composite endpoint, which is defined as either CV death or HF hospitalization due to HF.	
End point type	Primary
End point timeframe: up to End of Study (78 months)	

End point values	Combination Aliskiren / Enalapril	Aliskiren	Enalapril	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2340	2340	2336	
Units: participants				
Primary Composite	770	791	808	
CV death	512	562	547	
1st HF Hospitalization	430	442	452	

### Statistical analyses

Statistical analysis title	Superiority Statistical Analysis
Statistical analysis description: Superiority of Combination Aliskiren / Enalapril versus Enalapril monotherapy	
Comparison groups	Combination Aliskiren / Enalapril v Enalapril



Number of subjects included in analysis	4676
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1724
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.93
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.85
upper limit	1.03

<b>Statistical analysis title</b>	Superiority Non-Diabetic patients
Statistical analysis description:	
Superiority of Combination Aliskiren / Enalapril versus Enalapril monotherapy Non-Diabetic patients	
Comparison groups	Combination Aliskiren / Enalapril v Enalapril
Number of subjects included in analysis	4676
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.4579
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.85
upper limit	1.07

<b>Statistical analysis title</b>	Non-Inferiority Statistical Analysis
Statistical analysis description:	
Non-Inferiority Statistical Analysis of Aliskiren monotherapy versus Enalapril monotherapy	
Comparison groups	Aliskiren v Enalapril
Number of subjects included in analysis	4676
Analysis specification	Pre-specified
Analysis type	non-inferiority <sup>[1]</sup>
P-value	= 0.0368
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.99
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.9
upper limit	1.1

Notes:

[1] - Pre-specified Non-inferiority margin 1.104 is used.

<b>Statistical analysis title</b>	Superiority Statistical Analysis
Statistical analysis description:	
Superiority Statistical Analysis of Aliskiren monotherapy versus Enalapril monotherapy	
Comparison groups	Aliskiren v Enalapril
Number of subjects included in analysis	4676
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9118
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.99
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.9
upper limit	1.1

### **Secondary: Change from baseline to Month 12 for the Kansas City Cardiomyopathy Questionnaire (KCCQ) clinical summary score**

End point title	Change from baseline to Month 12 for the Kansas City Cardiomyopathy Questionnaire (KCCQ) clinical summary score
End point description:	
Change from baseline to Month 12 for the Kansas City Cardiomyopathy Questionnaire (KCCQ) clinical summary score. KCCQ is a 23-item, self-administered instrument that quantifies physical function, symptoms (frequency, severity and recent change), social function, self-efficacy and knowledge, and quality of life. KCCQ clinical summary score is a composite assessment of physical limitations and total symptom scores. Scores are transformed to a range of 0-100, in which higher scores reflect better health status.	
End point type	Secondary
End point timeframe:	
Baseline, Month 12	

<b>End point values</b>	Combination Aliskiren / Enalapril	Aliskiren	Enalapril	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2340	2340	2336	
Units: KCCQ Score				
least squares mean (standard error)	-5.04 (± 0.56)	-6.03 (± 0.57)	-5.01 (± 0.55)	

### **Statistical analyses**

No statistical analyses for this end point

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**Secondary: All Cause Death**

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End point title	All Cause Death
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End point description:

Number of patients - All-cause death. All-cause death is common in Heart Failure HF patients this measures how many patients had this event.

End point type	Secondary
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End point timeframe:

up to end of study (78 months)

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End point values	Combination Aliskiren / Enalapril	Aliskiren	Enalapril	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2340	2340	2336	
Units: participants	595	654	646	

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**Statistical analyses**

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No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Adverse events are collected from First Patient First Visit (FPFV) until Last Patient Last Visit (LPLV). All adverse events reported in this record are from date of First Patient First Treatment until Last Patient Last Visit

Assessment type	Systematic
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### Dictionary used

Dictionary name	MedDRA
Dictionary version	18.1

### Reporting groups

Reporting group title	Combination
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Reporting group description:

Combination

Reporting group title	Aliskiren
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Reporting group description:

Aliskiren

Reporting group title	Enalapril
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Reporting group description:

Enalapril

Serious adverse events	Combination	Aliskiren	Enalapril
Total subjects affected by serious adverse events			
subjects affected / exposed	1466 / 2347 (62.46%)	1504 / 2348 (64.05%)	1501 / 2345 (64.01%)
number of deaths (all causes)	349	403	392
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute myeloid leukaemia			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Adenocarcinoma gastric			
subjects affected / exposed	2 / 2347 (0.09%)	1 / 2348 (0.04%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenocarcinoma of appendix			

subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Adenocarcinoma of colon			
subjects affected / exposed	3 / 2347 (0.13%)	8 / 2348 (0.34%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 3	0 / 9	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adrenal adenoma			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	1 / 2345 (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
Basal cell carcinoma			
subjects affected / exposed	2 / 2347 (0.09%)	5 / 2348 (0.21%)	3 / 2345 (0.13%)
occurrences causally related to treatment / all	0 / 2	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign ear neoplasm			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Benign lung neoplasm			
subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	0 / 2345 (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
Benign neoplasm of bladder			
subjects affected / exposed	0 / 2347 (0.00%)	2 / 2348 (0.09%)	0 / 2345 (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
Benign neoplasm of skin			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Benign neoplasm of spinal cord			

subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Benign neoplasm of thyroid gland			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Benign pancreatic neoplasm			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Benign renal neoplasm			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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 salivary gland neoplasm			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	1 / 2345 (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
Bile duct adenocarcinoma			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Bile duct cancer			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	1 / 2345 (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
Bladder cancer			
subjects affected / exposed	3 / 2347 (0.13%)	4 / 2348 (0.17%)	6 / 2345 (0.26%)
occurrences causally related to treatment / all	0 / 3	0 / 5	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder cancer recurrent			

subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Bladder neoplasm			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Bladder papilloma			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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 transitional cell carcinoma			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	1 / 2345 (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
Bone cancer			
subjects affected / exposed	2 / 2347 (0.09%)	0 / 2348 (0.00%)	0 / 2345 (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
Brain neoplasm			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Brain neoplasm malignant			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Breast cancer			
subjects affected / exposed	1 / 2347 (0.04%)	3 / 2348 (0.13%)	3 / 2345 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast cancer female			

subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Bronchial carcinoma			
subjects affected / exposed	2 / 2347 (0.09%)	0 / 2348 (0.00%)	7 / 2345 (0.30%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carcinoma in situ of penis			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Carcinoma in situ of skin			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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 valve fibroelastoma			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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 tumour			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Cholangiocarcinoma			
subjects affected / exposed	2 / 2347 (0.09%)	2 / 2348 (0.09%)	1 / 2345 (0.04%)
occurrences causally related to treatment / all	0 / 8	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic lymphocytic leukaemia			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Colon adenoma			



subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon cancer			
subjects affected / exposed	10 / 2347 (0.43%)	4 / 2348 (0.17%)	7 / 2345 (0.30%)
occurrences causally related to treatment / all	0 / 10	0 / 4	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon cancer metastatic			
subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	0 / 2345 (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
Colon cancer recurrent			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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 adenocarcinoma			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Colorectal cancer			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Extranodal marginal zone B-cell lymphoma (MALT type)			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Gallbladder cancer			
subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	0 / 2345 (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
Gastric adenoma			

subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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 cancer			
subjects affected / exposed	6 / 2347 (0.26%)	3 / 2348 (0.13%)	3 / 2345 (0.13%)
occurrences causally related to treatment / all	0 / 6	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal cancer metastatic			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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 carcinoma			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Glioblastoma			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Glioma			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Haemangioma			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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 cancer			
subjects affected / exposed	4 / 2347 (0.17%)	2 / 2348 (0.09%)	1 / 2345 (0.04%)
occurrences causally related to treatment / all	0 / 4	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic cancer metastatic			

subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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 neoplasm			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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 cancer			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Hepatocellular carcinoma			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	1 / 2345 (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
Hodgkin's disease			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Hypopharyngeal cancer			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Infected neoplasm			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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 adenocarcinoma			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Keratoacanthoma			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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 benign neoplasm			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Laryngeal cancer			
subjects affected / exposed	2 / 2347 (0.09%)	0 / 2348 (0.00%)	0 / 2345 (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
Laryngeal squamous cell carcinoma			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Lentigo maligna			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Lip and/or oral cavity cancer			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Lip neoplasm malignant stage unspecified			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Lipoma			

subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	1 / 2345 (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
Lung adenocarcinoma			
subjects affected / exposed	2 / 2347 (0.09%)	1 / 2348 (0.04%)	1 / 2345 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung adenocarcinoma metastatic			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Lung cancer metastatic			
subjects affected / exposed	0 / 2347 (0.00%)	2 / 2348 (0.09%)	0 / 2345 (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 carcinoma cell type unspecified stage IV			
subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	0 / 2345 (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
Lung neoplasm			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Lung neoplasm malignant			
subjects affected / exposed	9 / 2347 (0.38%)	9 / 2348 (0.38%)	12 / 2345 (0.51%)
occurrences causally related to treatment / all	0 / 9	0 / 9	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphoma			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	1 / 2345 (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
Malignant melanoma			

subjects affected / exposed	1 / 2347 (0.04%)	3 / 2348 (0.13%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant neoplasm of auricular cartilage			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Malignant neoplasm of renal pelvis			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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 palate neoplasm			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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 pleural effusion			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Mediastinum neoplasm			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Meningioma benign			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Metastases to bone			

subjects affected / exposed	0 / 2347 (0.00%)	3 / 2348 (0.13%)	0 / 2345 (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
Metastases to bone marrow			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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 central nervous system			
subjects affected / exposed	0 / 2347 (0.00%)	2 / 2348 (0.09%)	1 / 2345 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to liver			
subjects affected / exposed	0 / 2347 (0.00%)	7 / 2348 (0.30%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 7	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to lung			
subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to lymph nodes			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	1 / 2345 (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
Metastases to peritoneum			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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 spine			

subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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 malignant melanoma			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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 pain			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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 squamous cell carcinoma			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	1 / 2345 (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
Myelodysplastic syndrome			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Myeloproliferative disorder			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Nasopharyngeal cancer			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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 malignant			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuroendocrine carcinoma			



subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	1 / 2345 (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
Non-Hodgkin's lymphoma			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Non-small cell lung cancer			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-small cell lung cancer stage IV			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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 carcinoma			
subjects affected / exposed	3 / 2347 (0.13%)	4 / 2348 (0.17%)	3 / 2345 (0.13%)
occurrences causally related to treatment / all	0 / 3	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian cancer			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Pancreatic carcinoma			
subjects affected / exposed	4 / 2347 (0.17%)	2 / 2348 (0.09%)	5 / 2345 (0.21%)
occurrences causally related to treatment / all	0 / 6	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic carcinoma metastatic			
subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	0 / 2345 (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
Pancreatic carcinoma stage IV			

subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Papillary thyroid cancer			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Penile cancer			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Pineal parenchymal neoplasm malignant			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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	5 / 2347 (0.21%)	1 / 2348 (0.04%)	0 / 2345 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural mesothelioma			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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			
subjects affected / exposed	6 / 2347 (0.26%)	7 / 2348 (0.30%)	19 / 2345 (0.81%)
occurrences causally related to treatment / all	1 / 6	0 / 8	0 / 20
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer metastatic			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatic adenoma			

subjects affected / exposed	1 / 2347 (0.04%)	2 / 2348 (0.09%)	1 / 2345 (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
Rectal adenocarcinoma			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal cancer			
subjects affected / exposed	2 / 2347 (0.09%)	3 / 2348 (0.13%)	3 / 2345 (0.13%)
occurrences causally related to treatment / all	0 / 3	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectosigmoid cancer			
subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	1 / 2345 (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
Renal cancer			
subjects affected / exposed	5 / 2347 (0.21%)	1 / 2348 (0.04%)	1 / 2345 (0.04%)
occurrences causally related to treatment / all	0 / 5	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal cancer metastatic			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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 cell carcinoma			
subjects affected / exposed	2 / 2347 (0.09%)	4 / 2348 (0.17%)	3 / 2345 (0.13%)
occurrences causally related to treatment / all	0 / 2	2 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal neoplasm			
subjects affected / exposed	1 / 2347 (0.04%)	2 / 2348 (0.09%)	0 / 2345 (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 adenoma			

subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Sinus cancer metastatic			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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 cancer			
subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	1 / 2345 (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
Small cell lung cancer recurrent			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Squamous cell carcinoma			
subjects affected / exposed	2 / 2347 (0.09%)	0 / 2348 (0.00%)	5 / 2345 (0.21%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of lung			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of skin			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	1 / 2345 (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
Thyroid cancer			
subjects affected / exposed	2 / 2347 (0.09%)	0 / 2348 (0.00%)	0 / 2345 (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
Thyroid neoplasm			

subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Tongue neoplasm malignant stage unspecified			
subjects affected / exposed	0 / 2347 (0.00%)	2 / 2348 (0.09%)	0 / 2345 (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
Transitional cell carcinoma			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Tumour flare			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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 pain			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Uterine cancer			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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 leiomyoma			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Vascular disorders			
Accelerated hypertension			

subjects affected / exposed	5 / 2347 (0.21%)	1 / 2348 (0.04%)	1 / 2345 (0.04%)
occurrences causally related to treatment / all	0 / 5	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aneurysm ruptured			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Aortic aneurysm			
subjects affected / exposed	0 / 2347 (0.00%)	8 / 2348 (0.34%)	8 / 2345 (0.34%)
occurrences causally related to treatment / all	0 / 0	0 / 8	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic aneurysm rupture			
subjects affected / exposed	2 / 2347 (0.09%)	1 / 2348 (0.04%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic arteriosclerosis			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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 dilatation			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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 dissection			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic rupture			
subjects affected / exposed	0 / 2347 (0.00%)	2 / 2348 (0.09%)	0 / 2345 (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
Aortic stenosis			

subjects affected / exposed	2 / 2347 (0.09%)	3 / 2348 (0.13%)	1 / 2345 (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
Aortic thrombosis			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Arterial insufficiency			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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 thrombosis			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Arteriosclerosis			
subjects affected / exposed	3 / 2347 (0.13%)	1 / 2348 (0.04%)	0 / 2345 (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
Arteriovenous fistula			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Arteritis			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Bleeding varicose vein			

subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Circulatory collapse			
subjects affected / exposed	7 / 2347 (0.30%)	3 / 2348 (0.13%)	3 / 2345 (0.13%)
occurrences causally related to treatment / all	2 / 7	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deep vein thrombosis			
subjects affected / exposed	3 / 2347 (0.13%)	5 / 2348 (0.21%)	4 / 2345 (0.17%)
occurrences causally related to treatment / all	0 / 3	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic vascular disorder			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Embolism arterial			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Embolism venous			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Extremity necrosis			
subjects affected / exposed	2 / 2347 (0.09%)	2 / 2348 (0.09%)	0 / 2345 (0.00%)
occurrences causally related to treatment / all	0 / 3	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femoral artery embolism			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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	2 / 2347 (0.09%)	3 / 2348 (0.13%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematoma			
subjects affected / exposed	5 / 2347 (0.21%)	1 / 2348 (0.04%)	4 / 2345 (0.17%)
occurrences causally related to treatment / all	0 / 5	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemodynamic instability			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Hypertension			
subjects affected / exposed	17 / 2347 (0.72%)	13 / 2348 (0.55%)	10 / 2345 (0.43%)
occurrences causally related to treatment / all	0 / 19	1 / 13	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive crisis			
subjects affected / exposed	7 / 2347 (0.30%)	4 / 2348 (0.17%)	3 / 2345 (0.13%)
occurrences causally related to treatment / all	0 / 7	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive emergency			
subjects affected / exposed	2 / 2347 (0.09%)	0 / 2348 (0.00%)	1 / 2345 (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
Hypotension			
subjects affected / exposed	37 / 2347 (1.58%)	49 / 2348 (2.09%)	26 / 2345 (1.11%)
occurrences causally related to treatment / all	9 / 38	18 / 52	9 / 34
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypovolaemic shock			
subjects affected / exposed	1 / 2347 (0.04%)	4 / 2348 (0.17%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Iliac artery embolism			

subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Iliac artery occlusion			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	1 / 2345 (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
Intermittent claudication			
subjects affected / exposed	5 / 2347 (0.21%)	5 / 2348 (0.21%)	3 / 2345 (0.13%)
occurrences causally related to treatment / all	0 / 7	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemia			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Ischaemic limb pain			
subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	0 / 2345 (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
Orthostatic hypotension			
subjects affected / exposed	5 / 2347 (0.21%)	3 / 2348 (0.13%)	4 / 2345 (0.17%)
occurrences causally related to treatment / all	1 / 5	1 / 3	2 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral arterial occlusive disease			
subjects affected / exposed	18 / 2347 (0.77%)	13 / 2348 (0.55%)	11 / 2345 (0.47%)
occurrences causally related to treatment / all	0 / 22	0 / 15	0 / 18
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral artery aneurysm			
subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	1 / 2345 (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
Peripheral artery stenosis			

subjects affected / exposed	5 / 2347 (0.21%)	2 / 2348 (0.09%)	3 / 2345 (0.13%)
occurrences causally related to treatment / all	0 / 5	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral artery thrombosis			
subjects affected / exposed	0 / 2347 (0.00%)	3 / 2348 (0.13%)	4 / 2345 (0.17%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral embolism			
subjects affected / exposed	4 / 2347 (0.17%)	2 / 2348 (0.09%)	3 / 2345 (0.13%)
occurrences causally related to treatment / all	0 / 4	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral ischaemia			
subjects affected / exposed	5 / 2347 (0.21%)	8 / 2348 (0.34%)	3 / 2345 (0.13%)
occurrences causally related to treatment / all	0 / 6	0 / 9	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral vascular disorder			
subjects affected / exposed	1 / 2347 (0.04%)	2 / 2348 (0.09%)	1 / 2345 (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
Peripheral venous disease			
subjects affected / exposed	0 / 2347 (0.00%)	4 / 2348 (0.17%)	4 / 2345 (0.17%)
occurrences causally related to treatment / all	0 / 0	1 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post thrombotic syndrome			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Secondary hypertension			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Shock			

subjects affected / exposed	2 / 2347 (0.09%)	1 / 2348 (0.04%)	1 / 2345 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Shock haemorrhagic			
subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subclavian artery stenosis			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Thrombophlebitis superficial			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Thrombosis			
subjects affected / exposed	2 / 2347 (0.09%)	1 / 2348 (0.04%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicophlebitis			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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 ulceration			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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 / 2347 (0.00%)	3 / 2348 (0.13%)	1 / 2345 (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
Vascular rupture			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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 thrombosis			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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 limb			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Surgical and medical procedures			
Heart transplant			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	1 / 2345 (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 insertion			
subjects affected / exposed	0 / 2347 (0.00%)	3 / 2348 (0.13%)	1 / 2345 (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
General disorders and administration site conditions			
Abasia			
subjects affected / exposed	0 / 2347 (0.00%)	2 / 2348 (0.09%)	0 / 2345 (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

Accidental death			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	1 / 2345 (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
Asthenia			
subjects affected / exposed	8 / 2347 (0.34%)	5 / 2348 (0.21%)	4 / 2345 (0.17%)
occurrences causally related to treatment / all	0 / 8	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain death			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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 complication associated with device			
subjects affected / exposed	2 / 2347 (0.09%)	1 / 2348 (0.04%)	0 / 2345 (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
Cardiac death			
subjects affected / exposed	51 / 2347 (2.17%)	68 / 2348 (2.90%)	87 / 2345 (3.71%)
occurrences causally related to treatment / all	0 / 51	1 / 68	1 / 87
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest discomfort			
subjects affected / exposed	2 / 2347 (0.09%)	0 / 2348 (0.00%)	0 / 2345 (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
Chest pain			
subjects affected / exposed	2 / 2347 (0.09%)	3 / 2348 (0.13%)	1 / 2345 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			
subjects affected / exposed	75 / 2347 (3.20%)	84 / 2348 (3.58%)	82 / 2345 (3.50%)
occurrences causally related to treatment / all	1 / 75	0 / 84	0 / 82
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device battery issue			

subjects affected / exposed	13 / 2347 (0.55%)	9 / 2348 (0.38%)	14 / 2345 (0.60%)
occurrences causally related to treatment / all	0 / 13	0 / 9	0 / 16
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device breakage			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	1 / 2345 (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
Device defective			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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 dislocation			
subjects affected / exposed	1 / 2347 (0.04%)	4 / 2348 (0.17%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device electrical impedance issue			
subjects affected / exposed	2 / 2347 (0.09%)	0 / 2348 (0.00%)	0 / 2345 (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
Device end of service			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device failure			
subjects affected / exposed	4 / 2347 (0.17%)	0 / 2348 (0.00%)	0 / 2345 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device inappropriate shock delivery			
subjects affected / exposed	1 / 2347 (0.04%)	4 / 2348 (0.17%)	3 / 2345 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device issue			

subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	1 / 2345 (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
Device lead damage			
subjects affected / exposed	1 / 2347 (0.04%)	3 / 2348 (0.13%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device lead issue			
subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device malfunction			
subjects affected / exposed	7 / 2347 (0.30%)	10 / 2348 (0.43%)	9 / 2345 (0.38%)
occurrences causally related to treatment / all	0 / 7	0 / 10	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device signal detection issue			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Device stimulation issue			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Disease progression			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Drug withdrawal syndrome			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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>Fatigue</b>			
subjects affected / exposed	5 / 2347 (0.21%)	1 / 2348 (0.04%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 5	1 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Feeling abnormal</b>			
subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	0 / 2345 (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
<b>Gait disturbance</b>			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
<b>General physical health deterioration</b>			
subjects affected / exposed	3 / 2347 (0.13%)	3 / 2348 (0.13%)	7 / 2345 (0.30%)
occurrences causally related to treatment / all	0 / 3	0 / 3	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Generalised oedema</b>			
subjects affected / exposed	2 / 2347 (0.09%)	2 / 2348 (0.09%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 3	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Hernia</b>			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
<b>Hypothermia</b>			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
<b>Ill-defined disorder</b>			

subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Impaired healing			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	1 / 2345 (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 erosion			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Implant site haemorrhage			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Implant site necrosis			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Implant site pain			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Implant site ulcer			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Incarcerated hernia			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Inflammation			

subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Influenza like illness			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Injury associated with device			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Lead dislodgement			
subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	1 / 2345 (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
Localised oedema			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Malaise			
subjects affected / exposed	5 / 2347 (0.21%)	4 / 2348 (0.17%)	1 / 2345 (0.04%)
occurrences causally related to treatment / all	0 / 6	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Medical device complication			
subjects affected / exposed	4 / 2347 (0.17%)	1 / 2348 (0.04%)	1 / 2345 (0.04%)
occurrences causally related to treatment / all	0 / 5	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Medical device site thrombosis			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Metaplasia			

subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	0 / 2345 (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
Multi-organ failure			
subjects affected / exposed	21 / 2347 (0.89%)	15 / 2348 (0.64%)	12 / 2345 (0.51%)
occurrences causally related to treatment / all	0 / 21	0 / 15	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Necrosis			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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-cardiac chest pain			
subjects affected / exposed	13 / 2347 (0.55%)	15 / 2348 (0.64%)	22 / 2345 (0.94%)
occurrences causally related to treatment / all	0 / 15	0 / 16	0 / 24
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Oedema peripheral			
subjects affected / exposed	9 / 2347 (0.38%)	6 / 2348 (0.26%)	3 / 2345 (0.13%)
occurrences causally related to treatment / all	0 / 13	1 / 7	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Organ failure			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Peripheral swelling			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			

subjects affected / exposed	5 / 2347 (0.21%)	8 / 2348 (0.34%)	7 / 2345 (0.30%)
occurrences causally related to treatment / all	0 / 5	0 / 9	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stent-graft endoleak			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Sudden cardiac death			
subjects affected / exposed	38 / 2347 (1.62%)	39 / 2348 (1.66%)	50 / 2345 (2.13%)
occurrences causally related to treatment / all	2 / 38	5 / 39	3 / 50
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden death			
subjects affected / exposed	98 / 2347 (4.18%)	89 / 2348 (3.79%)	86 / 2345 (3.67%)
occurrences causally related to treatment / all	0 / 98	0 / 89	1 / 86
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombosis in device			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Ulcer			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Ulcer haemorrhage			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	1 / 2345 (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
Undersensing			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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 stent restenosis			

subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Vascular stent stenosis			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Vascular stent thrombosis			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Allergy to venom			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Anaphylactic reaction			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	1 / 2345 (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
Anaphylactic shock			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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 hypersensitivity			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Heart transplant rejection			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Transplant rejection			

subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
<b>Social circumstances</b>			
Immobile			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	1 / 2345 (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
Treatment noncompliance			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
<b>Reproductive system and breast disorders</b>			
Acquired hydrocele			
subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	0 / 2345 (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
Benign prostatic hyperplasia			
subjects affected / exposed	2 / 2347 (0.09%)	9 / 2348 (0.38%)	7 / 2345 (0.30%)
occurrences causally related to treatment / all	0 / 2	0 / 10	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast hyperplasia			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Mammary fistula			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Menorrhagia			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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

Metrorrhagia			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	1 / 2345 (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
Ovarian cyst			
subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	0 / 2345 (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
Postmenopausal haemorrhage			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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 / 2347 (0.00%)	1 / 2348 (0.04%)	1 / 2345 (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
Prostatitis			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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 / 2347 (0.00%)	1 / 2348 (0.04%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectocele			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Scrotal oedema			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Spermatocele			



subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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 polyp			
subjects affected / exposed	2 / 2347 (0.09%)	0 / 2348 (0.00%)	0 / 2345 (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
Respiratory, thoracic and mediastinal disorders			
Acute pulmonary oedema			
subjects affected / exposed	20 / 2347 (0.85%)	20 / 2348 (0.85%)	17 / 2345 (0.72%)
occurrences causally related to treatment / all	0 / 24	2 / 25	0 / 18
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	1 / 2345 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute respiratory failure			
subjects affected / exposed	13 / 2347 (0.55%)	8 / 2348 (0.34%)	14 / 2345 (0.60%)
occurrences causally related to treatment / all	0 / 15	0 / 12	0 / 17
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alveolitis			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Apnoea			
subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	0 / 2345 (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
Asphyxia			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Asthma			

subjects affected / exposed	4 / 2347 (0.17%)	8 / 2348 (0.34%)	5 / 2345 (0.21%)
occurrences causally related to treatment / all	1 / 4	0 / 11	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthmatic crisis			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Bronchiectasis			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	1 / 2345 (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
Bronchitis chronic			
subjects affected / exposed	2 / 2347 (0.09%)	1 / 2348 (0.04%)	8 / 2345 (0.34%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopleural fistula			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Bronchospasm			
subjects affected / exposed	2 / 2347 (0.09%)	1 / 2348 (0.04%)	0 / 2345 (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
Cheyne-Stokes respiration			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary disease			
subjects affected / exposed	32 / 2347 (1.36%)	32 / 2348 (1.36%)	43 / 2345 (1.83%)
occurrences causally related to treatment / all	0 / 42	1 / 41	0 / 60
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic respiratory failure			

subjects affected / exposed	0 / 2347 (0.00%)	2 / 2348 (0.09%)	0 / 2345 (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
Cough			
subjects affected / exposed	6 / 2347 (0.26%)	2 / 2348 (0.09%)	3 / 2345 (0.13%)
occurrences causally related to treatment / all	1 / 6	0 / 2	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diaphragmatic paralysis			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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	54 / 2347 (2.30%)	46 / 2348 (1.96%)	35 / 2345 (1.49%)
occurrences causally related to treatment / all	0 / 65	0 / 59	0 / 45
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea at rest			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Dyspnoea exertional			
subjects affected / exposed	1 / 2347 (0.04%)	2 / 2348 (0.09%)	3 / 2345 (0.13%)
occurrences causally related to treatment / all	0 / 1	1 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea paroxysmal nocturnal			
subjects affected / exposed	0 / 2347 (0.00%)	2 / 2348 (0.09%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Emphysema			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Epistaxis			

subjects affected / exposed	4 / 2347 (0.17%)	3 / 2348 (0.13%)	8 / 2345 (0.34%)
occurrences causally related to treatment / all	0 / 4	0 / 3	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	4 / 2347 (0.17%)	2 / 2348 (0.09%)	5 / 2345 (0.21%)
occurrences causally related to treatment / all	0 / 4	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemothorax			
subjects affected / exposed	1 / 2347 (0.04%)	2 / 2348 (0.09%)	1 / 2345 (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
Hiccups			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Hydrothorax			
subjects affected / exposed	3 / 2347 (0.13%)	2 / 2348 (0.09%)	3 / 2345 (0.13%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercapnia			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Hyperventilation			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Hypoxia			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	1 / 2345 (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
Idiopathic pulmonary fibrosis			

subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Interstitial lung disease			
subjects affected / exposed	2 / 2347 (0.09%)	0 / 2348 (0.00%)	3 / 2345 (0.13%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngeal oedema			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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 disorder			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung infiltration			
subjects affected / exposed	0 / 2347 (0.00%)	2 / 2348 (0.09%)	0 / 2345 (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
Mediastinal mass			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Nasal septum deviation			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Organising pneumonia			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Oropharyngeal pain			

subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Orthopnoea			
subjects affected / exposed	3 / 2347 (0.13%)	0 / 2348 (0.00%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngeal oedema			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Pleural effusion			
subjects affected / exposed	10 / 2347 (0.43%)	11 / 2348 (0.47%)	12 / 2345 (0.51%)
occurrences causally related to treatment / all	0 / 13	0 / 13	0 / 17
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleurisy			
subjects affected / exposed	2 / 2347 (0.09%)	2 / 2348 (0.09%)	3 / 2345 (0.13%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleurocutaneous fistula			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Pneumomediastinum			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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	5 / 2347 (0.21%)	6 / 2348 (0.26%)	4 / 2345 (0.17%)
occurrences causally related to treatment / all	0 / 5	0 / 6	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			

subjects affected / exposed	1 / 2347 (0.04%)	3 / 2348 (0.13%)	1 / 2345 (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
Pneumothorax			
subjects affected / exposed	1 / 2347 (0.04%)	3 / 2348 (0.13%)	4 / 2345 (0.17%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax spontaneous			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Productive cough			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	1 / 2345 (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 alveolar haemorrhage			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Pulmonary arterial hypertension			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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 artery thrombosis			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Pulmonary congestion			
subjects affected / exposed	3 / 2347 (0.13%)	1 / 2348 (0.04%)	1 / 2345 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			

subjects affected / exposed	17 / 2347 (0.72%)	18 / 2348 (0.77%)	9 / 2345 (0.38%)
occurrences causally related to treatment / all	0 / 18	0 / 18	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary fibrosis			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Pulmonary haematoma			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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 hypertension			
subjects affected / exposed	6 / 2347 (0.26%)	4 / 2348 (0.17%)	4 / 2345 (0.17%)
occurrences causally related to treatment / all	0 / 6	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary mass			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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 oedema			
subjects affected / exposed	27 / 2347 (1.15%)	27 / 2348 (1.15%)	14 / 2345 (0.60%)
occurrences causally related to treatment / all	0 / 37	0 / 30	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary venous thrombosis			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Respiratory arrest			
subjects affected / exposed	1 / 2347 (0.04%)	2 / 2348 (0.09%)	0 / 2345 (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
Respiratory distress			



subjects affected / exposed	0 / 2347 (0.00%)	4 / 2348 (0.17%)	3 / 2345 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	16 / 2347 (0.68%)	16 / 2348 (0.68%)	26 / 2345 (1.11%)
occurrences causally related to treatment / all	0 / 16	0 / 16	2 / 28
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sleep apnoea syndrome			
subjects affected / exposed	3 / 2347 (0.13%)	2 / 2348 (0.09%)	1 / 2345 (0.04%)
occurrences causally related to treatment / all	1 / 3	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Snoring			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Suffocation feeling			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Vocal cord leukoplakia			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Psychiatric disorders			
Abulia			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Acute psychosis			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Adjustment disorder			

subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Alcohol abuse			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Alcohol withdrawal syndrome			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Alcoholism			
subjects affected / exposed	0 / 2347 (0.00%)	2 / 2348 (0.09%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anxiety			
subjects affected / exposed	2 / 2347 (0.09%)	2 / 2348 (0.09%)	4 / 2345 (0.17%)
occurrences causally related to treatment / all	0 / 6	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anxiety disorder			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Apathy			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Bipolar disorder			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Catatonia			

subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Completed suicide			
subjects affected / exposed	0 / 2347 (0.00%)	2 / 2348 (0.09%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Confusional state			
subjects affected / exposed	4 / 2347 (0.17%)	4 / 2348 (0.17%)	3 / 2345 (0.13%)
occurrences causally related to treatment / all	0 / 5	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium			
subjects affected / exposed	1 / 2347 (0.04%)	3 / 2348 (0.13%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delusion			
subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	0 / 2345 (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
Depression			
subjects affected / exposed	2 / 2347 (0.09%)	6 / 2348 (0.26%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 2	0 / 6	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disorientation			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	1 / 2345 (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
Fear			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Major depression			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Mental status changes			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Mood disorder due to a general medical condition			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Psychotic disorder			
subjects affected / exposed	2 / 2347 (0.09%)	3 / 2348 (0.13%)	0 / 2345 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Restlessness			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Schizophrenia			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Somatisation disorder			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Suicide attempt			
subjects affected / exposed	2 / 2347 (0.09%)	0 / 2348 (0.00%)	0 / 2345 (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
Hepatobiliary disorders			
Acute hepatic failure			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Bile duct obstruction			
subjects affected / exposed	0 / 2347 (0.00%)	2 / 2348 (0.09%)	1 / 2345 (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
Bile duct stenosis			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bile duct stone			
subjects affected / exposed	3 / 2347 (0.13%)	3 / 2348 (0.13%)	0 / 2345 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary cirrhosis			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Biliary colic			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	1 / 2345 (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
Biliary dilatation			

subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	1 / 2345 (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
Cholangitis			
subjects affected / exposed	2 / 2347 (0.09%)	5 / 2348 (0.21%)	3 / 2345 (0.13%)
occurrences causally related to treatment / all	0 / 4	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis acute			
subjects affected / exposed	2 / 2347 (0.09%)	2 / 2348 (0.09%)	1 / 2345 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 2	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	7 / 2347 (0.30%)	4 / 2348 (0.17%)	8 / 2345 (0.34%)
occurrences causally related to treatment / all	0 / 7	0 / 4	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis acute			
subjects affected / exposed	9 / 2347 (0.38%)	9 / 2348 (0.38%)	9 / 2345 (0.38%)
occurrences causally related to treatment / all	0 / 9	0 / 9	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis chronic			
subjects affected / exposed	2 / 2347 (0.09%)	1 / 2348 (0.04%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	18 / 2347 (0.77%)	15 / 2348 (0.64%)	13 / 2345 (0.55%)
occurrences causally related to treatment / all	1 / 18	0 / 15	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholestasis			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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 hepatitis			

subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Cirrhosis alcoholic			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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-induced liver injury			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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 cirrhosis			
subjects affected / exposed	3 / 2347 (0.13%)	2 / 2348 (0.09%)	6 / 2345 (0.26%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic congestion			
subjects affected / exposed	2 / 2347 (0.09%)	3 / 2348 (0.13%)	3 / 2345 (0.13%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			
subjects affected / exposed	4 / 2347 (0.17%)	2 / 2348 (0.09%)	3 / 2345 (0.13%)
occurrences causally related to treatment / all	0 / 4	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic function abnormal			
subjects affected / exposed	3 / 2347 (0.13%)	2 / 2348 (0.09%)	1 / 2345 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic steatosis			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Hepatitis			

subjects affected / exposed	3 / 2347 (0.13%)	0 / 2348 (0.00%)	1 / 2345 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis acute			
subjects affected / exposed	1 / 2347 (0.04%)	2 / 2348 (0.09%)	1 / 2345 (0.04%)
occurrences causally related to treatment / all	1 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis alcoholic			
subjects affected / exposed	2 / 2347 (0.09%)	0 / 2348 (0.00%)	0 / 2345 (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
Hepatocellular injury			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Hepatomegaly			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Hepatorenal failure			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Hepatorenal syndrome			
subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	3 / 2345 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatotoxicity			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Hyperbilirubinaemia			



subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	1 / 2345 (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
Ischaemic hepatitis			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	1 / 2345 (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
Jaundice			
subjects affected / exposed	2 / 2347 (0.09%)	3 / 2348 (0.13%)	5 / 2345 (0.21%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaundice cholestatic			
subjects affected / exposed	1 / 2347 (0.04%)	3 / 2348 (0.13%)	1 / 2345 (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
Jaundice hepatocellular			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Liver disorder			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	1 / 2345 (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
Liver injury			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Non-alcoholic steatohepatitis			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Portal hypertension			

subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	1 / 2345 (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
Investigations			
Anticoagulation drug level below therapeutic			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Anticoagulation drug level increased			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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 creatine phosphokinase increased			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatinine increased			
subjects affected / exposed	7 / 2347 (0.30%)	4 / 2348 (0.17%)	5 / 2345 (0.21%)
occurrences causally related to treatment / all	1 / 8	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood ethanol increased			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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 glucose increased			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood magnesium decreased			

subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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 potassium decreased			
subjects affected / exposed	0 / 2347 (0.00%)	2 / 2348 (0.09%)	0 / 2345 (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 potassium increased			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Blood urine			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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 urine present			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Brain natriuretic peptide increased			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
C-reactive protein increased			
subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	0 / 2345 (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
Cardiac murmur			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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 output decreased			

subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Cardioactive drug level increased			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Chest X-ray abnormal			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Coagulation test abnormal			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Coagulation time prolonged			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Ejection fraction abnormal			
subjects affected / exposed	1 / 2347 (0.04%)	2 / 2348 (0.09%)	1 / 2345 (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
Ejection fraction decreased			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	1 / 2345 (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
Electrocardiogram QRS complex prolonged			
subjects affected / exposed	1 / 2347 (0.04%)	2 / 2348 (0.09%)	1 / 2345 (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
Enterobacter test positive			

subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Gamma-glutamyltransferase increased			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Heart rate decreased			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Heart rate irregular			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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 enzyme increased			
subjects affected / exposed	2 / 2347 (0.09%)	0 / 2348 (0.00%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
International normalised ratio abnormal			
subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	0 / 2345 (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
International normalised ratio increased			
subjects affected / exposed	5 / 2347 (0.21%)	3 / 2348 (0.13%)	6 / 2345 (0.26%)
occurrences causally related to treatment / all	0 / 5	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lipase increased			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Oxygen saturation decreased			

subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Prostatic specific antigen increased			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Transaminases increased			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Urine output decreased			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Viral load increased			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Weight decreased			
subjects affected / exposed	3 / 2347 (0.13%)	3 / 2348 (0.13%)	1 / 2345 (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
Weight increased			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	3 / 2345 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
White blood cell count increased			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Injury, poisoning and procedural complications			
Accident			

subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Accidental exposure to product			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Accidental overdose			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Acetabulum fracture			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	1 / 2345 (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
Alcohol poisoning			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	1 / 2345 (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
Anastomotic complication			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Anastomotic ulcer			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Ankle fracture			
subjects affected / exposed	0 / 2347 (0.00%)	4 / 2348 (0.17%)	1 / 2345 (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
Avulsion fracture			

subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Bone contusion			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	1 / 2345 (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
Brain contusion			
subjects affected / exposed	3 / 2347 (0.13%)	1 / 2348 (0.04%)	0 / 2345 (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
Burns third degree			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Carbon monoxide poisoning			
subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	0 / 2345 (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
Cardiac function disturbance postoperative			
subjects affected / exposed	0 / 2347 (0.00%)	2 / 2348 (0.09%)	1 / 2345 (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
Cardiac procedure complication			
subjects affected / exposed	0 / 2347 (0.00%)	3 / 2348 (0.13%)	0 / 2345 (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
Carotid artery restenosis			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Cervical vertebral fracture			



subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	1 / 2345 (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
Chest injury			
subjects affected / exposed	2 / 2347 (0.09%)	0 / 2348 (0.00%)	0 / 2345 (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
Clavicle fracture			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Closed globe injury			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Comminuted fracture			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	1 / 2345 (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
Complications of transplanted heart			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Concussion			
subjects affected / exposed	3 / 2347 (0.13%)	0 / 2348 (0.00%)	1 / 2345 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Contusion			
subjects affected / exposed	5 / 2347 (0.21%)	2 / 2348 (0.09%)	0 / 2345 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery reocclusion			

subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Coronary artery restenosis			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	1 / 2345 (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
Coronary vascular graft occlusion			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Craniocerebral injury			
subjects affected / exposed	2 / 2347 (0.09%)	3 / 2348 (0.13%)	0 / 2345 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Excoriation			
subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	0 / 2345 (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
Extradural haematoma			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Facial bones fracture			
subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	0 / 2345 (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
Fall			
subjects affected / exposed	9 / 2347 (0.38%)	8 / 2348 (0.34%)	11 / 2345 (0.47%)
occurrences causally related to treatment / all	0 / 9	0 / 9	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femoral neck fracture			

subjects affected / exposed	5 / 2347 (0.21%)	3 / 2348 (0.13%)	3 / 2345 (0.13%)
occurrences causally related to treatment / all	0 / 5	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	9 / 2347 (0.38%)	10 / 2348 (0.43%)	6 / 2345 (0.26%)
occurrences causally related to treatment / all	0 / 9	0 / 11	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fibula fracture			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Foot fracture			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Forearm fracture			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Foreign body			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Fracture displacement			
subjects affected / exposed	3 / 2347 (0.13%)	0 / 2348 (0.00%)	1 / 2345 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fractured ischium			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Fractured sacrum			

subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal stoma complication			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Hand fracture			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Head injury			
subjects affected / exposed	7 / 2347 (0.30%)	3 / 2348 (0.13%)	3 / 2345 (0.13%)
occurrences causally related to treatment / all	0 / 7	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip fracture			
subjects affected / exposed	4 / 2347 (0.17%)	5 / 2348 (0.21%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 4	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Humerus fracture			
subjects affected / exposed	3 / 2347 (0.13%)	2 / 2348 (0.09%)	1 / 2345 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incision site haematoma			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Incisional hernia			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Injury			

subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	1 / 2345 (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
Intestinal anastomosis complication			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Joint dislocation			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint injury			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	1 / 2345 (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
Laceration			
subjects affected / exposed	0 / 2347 (0.00%)	2 / 2348 (0.09%)	0 / 2345 (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
Ligament injury			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Ligament sprain			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	1 / 2345 (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
Limb injury			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Limb traumatic amputation			

subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Lip injury			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Lower limb fracture			
subjects affected / exposed	3 / 2347 (0.13%)	2 / 2348 (0.09%)	1 / 2345 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar vertebral fracture			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	3 / 2345 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meniscus injury			
subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	0 / 2345 (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
Mouth injury			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Multiple fractures			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Multiple injuries			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Muscle injury			

subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Muscle rupture			
subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	0 / 2345 (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
Overdose			
subjects affected / exposed	4 / 2347 (0.17%)	9 / 2348 (0.38%)	0 / 2345 (0.00%)
occurrences causally related to treatment / all	0 / 4	1 / 9	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Patella fracture			
subjects affected / exposed	2 / 2347 (0.09%)	0 / 2348 (0.00%)	0 / 2345 (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
Pelvic fracture			
subjects affected / exposed	2 / 2347 (0.09%)	2 / 2348 (0.09%)	3 / 2345 (0.13%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periorbital haemorrhage			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Peripheral artery restenosis			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Periprosthetic fracture			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Pneumothorax traumatic			

subjects affected / exposed	0 / 2347 (0.00%)	3 / 2348 (0.13%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Poisoning			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Post procedural bile leak			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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 procedural complication			
subjects affected / exposed	2 / 2347 (0.09%)	1 / 2348 (0.04%)	1 / 2345 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural haematoma			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	1 / 2345 (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
Post procedural haematuria			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Post procedural haemorrhage			
subjects affected / exposed	1 / 2347 (0.04%)	4 / 2348 (0.17%)	1 / 2345 (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
Post-traumatic pain			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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 hernia			



subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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 ileus			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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 thoracic procedure complication			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Postoperative wound complication			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Procedural complication			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Procedural pain			
subjects affected / exposed	0 / 2347 (0.00%)	2 / 2348 (0.09%)	0 / 2345 (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
Product name confusion			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Pubis fracture			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Pulmonary contusion			

subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Radius fracture			
subjects affected / exposed	5 / 2347 (0.21%)	5 / 2348 (0.21%)	1 / 2345 (0.04%)
occurrences causally related to treatment / all	0 / 5	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory fume inhalation disorder			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Rib fracture			
subjects affected / exposed	8 / 2347 (0.34%)	6 / 2348 (0.26%)	8 / 2345 (0.34%)
occurrences causally related to treatment / all	0 / 8	0 / 6	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road traffic accident			
subjects affected / exposed	2 / 2347 (0.09%)	3 / 2348 (0.13%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sacroiliac fracture			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Scrotal haematoma			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Shunt stenosis			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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 abrasion			

subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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 injury			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Skull fracture			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Soft tissue injury			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Spinal compression fracture			
subjects affected / exposed	1 / 2347 (0.04%)	4 / 2348 (0.17%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord injury			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Spinal fracture			
subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	0 / 2345 (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
Subdural haematoma			
subjects affected / exposed	2 / 2347 (0.09%)	5 / 2348 (0.21%)	5 / 2345 (0.21%)
occurrences causally related to treatment / all	0 / 2	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haemorrhage			

subjects affected / exposed	1 / 2347 (0.04%)	2 / 2348 (0.09%)	1 / 2345 (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
Tendon rupture			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thermal burn			
subjects affected / exposed	2 / 2347 (0.09%)	0 / 2348 (0.00%)	1 / 2345 (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
Thoracic vertebral fracture			
subjects affected / exposed	3 / 2347 (0.13%)	0 / 2348 (0.00%)	0 / 2345 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tibia fracture			
subjects affected / exposed	1 / 2347 (0.04%)	2 / 2348 (0.09%)	3 / 2345 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tooth fracture			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Toxicity to various agents			
subjects affected / exposed	6 / 2347 (0.26%)	3 / 2348 (0.13%)	3 / 2345 (0.13%)
occurrences causally related to treatment / all	0 / 8	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transplant failure			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Traumatic fracture			

subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Traumatic haematoma			
subjects affected / exposed	2 / 2347 (0.09%)	0 / 2348 (0.00%)	0 / 2345 (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
Traumatic haemothorax			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Traumatic intracranial haemorrhage			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	1 / 2345 (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
Traumatic liver injury			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Traumatic shock			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Ulna fracture			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Underdose			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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 limb fracture			

subjects affected / exposed	1 / 2347 (0.04%)	4 / 2348 (0.17%)	1 / 2345 (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
Urethral stricture traumatic			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Vascular bypass dysfunction			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Vascular graft occlusion			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	1 / 2345 (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
Vascular pseudoaneurysm			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Vasoplegia syndrome			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Wound			
subjects affected / exposed	1 / 2347 (0.04%)	2 / 2348 (0.09%)	1 / 2345 (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
Wound haemorrhage			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Congenital, familial and genetic disorders			
Atrial septal defect			

subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Dermoid cyst			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Hydrocele			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	3 / 2345 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	6 / 2347 (0.26%)	18 / 2348 (0.77%)	16 / 2345 (0.68%)
occurrences causally related to treatment / all	0 / 6	0 / 19	0 / 16
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute left ventricular failure			
subjects affected / exposed	3 / 2347 (0.13%)	5 / 2348 (0.21%)	9 / 2345 (0.38%)
occurrences causally related to treatment / all	0 / 5	0 / 5	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute myocardial infarction			
subjects affected / exposed	49 / 2347 (2.09%)	40 / 2348 (1.70%)	46 / 2345 (1.96%)
occurrences causally related to treatment / all	0 / 50	1 / 41	1 / 47
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adams-Stokes syndrome			
subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	0 / 2345 (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
Angina pectoris			
subjects affected / exposed	35 / 2347 (1.49%)	33 / 2348 (1.41%)	37 / 2345 (1.58%)
occurrences causally related to treatment / all	0 / 41	1 / 39	1 / 51
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina unstable			

subjects affected / exposed	47 / 2347 (2.00%)	48 / 2348 (2.04%)	41 / 2345 (1.75%)
occurrences causally related to treatment / all	0 / 68	0 / 54	0 / 49
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic valve disease			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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 incompetence			
subjects affected / exposed	3 / 2347 (0.13%)	1 / 2348 (0.04%)	3 / 2345 (0.13%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic valve stenosis			
subjects affected / exposed	3 / 2347 (0.13%)	3 / 2348 (0.13%)	1 / 2345 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arrhythmia			
subjects affected / exposed	13 / 2347 (0.55%)	15 / 2348 (0.64%)	12 / 2345 (0.51%)
occurrences causally related to treatment / all	1 / 13	0 / 17	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arrhythmia supraventricular			
subjects affected / exposed	0 / 2347 (0.00%)	2 / 2348 (0.09%)	1 / 2345 (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
Arteriosclerosis coronary artery			
subjects affected / exposed	4 / 2347 (0.17%)	0 / 2348 (0.00%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	89 / 2347 (3.79%)	98 / 2348 (4.17%)	97 / 2345 (4.14%)
occurrences causally related to treatment / all	0 / 105	1 / 120	0 / 118
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial flutter			



subjects affected / exposed	15 / 2347 (0.64%)	21 / 2348 (0.89%)	11 / 2345 (0.47%)
occurrences causally related to treatment / all	1 / 17	0 / 25	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial tachycardia			
subjects affected / exposed	1 / 2347 (0.04%)	4 / 2348 (0.17%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial thrombosis			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block			
subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	3 / 2345 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block complete			
subjects affected / exposed	7 / 2347 (0.30%)	8 / 2348 (0.34%)	13 / 2345 (0.55%)
occurrences causally related to treatment / all	0 / 7	1 / 8	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block first degree			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Atrioventricular block second degree			
subjects affected / exposed	3 / 2347 (0.13%)	4 / 2348 (0.17%)	6 / 2345 (0.26%)
occurrences causally related to treatment / all	0 / 3	0 / 4	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bifascicular block			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Bradyarrhythmia			

subjects affected / exposed	1 / 2347 (0.04%)	3 / 2348 (0.13%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bradycardia			
subjects affected / exposed	12 / 2347 (0.51%)	12 / 2348 (0.51%)	9 / 2345 (0.38%)
occurrences causally related to treatment / all	0 / 12	2 / 13	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bundle branch block			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Bundle branch block left			
subjects affected / exposed	4 / 2347 (0.17%)	4 / 2348 (0.17%)	3 / 2345 (0.13%)
occurrences causally related to treatment / all	0 / 4	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac aneurysm			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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 arrest			
subjects affected / exposed	59 / 2347 (2.51%)	61 / 2348 (2.60%)	59 / 2345 (2.52%)
occurrences causally related to treatment / all	0 / 63	0 / 63	3 / 62
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac asthma			
subjects affected / exposed	2 / 2347 (0.09%)	4 / 2348 (0.17%)	1 / 2345 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac discomfort			
subjects affected / exposed	3 / 2347 (0.13%)	3 / 2348 (0.13%)	0 / 2345 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorder			

subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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 failure			
subjects affected / exposed	480 / 2347 (20.45%)	521 / 2348 (22.19%)	503 / 2345 (21.45%)
occurrences causally related to treatment / all	15 / 892	17 / 996	20 / 903
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure acute			
subjects affected / exposed	54 / 2347 (2.30%)	43 / 2348 (1.83%)	60 / 2345 (2.56%)
occurrences causally related to treatment / all	1 / 75	1 / 56	2 / 80
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure chronic			
subjects affected / exposed	120 / 2347 (5.11%)	125 / 2348 (5.32%)	122 / 2345 (5.20%)
occurrences causally related to treatment / all	3 / 209	3 / 189	8 / 220
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive			
subjects affected / exposed	76 / 2347 (3.24%)	85 / 2348 (3.62%)	79 / 2345 (3.37%)
occurrences causally related to treatment / all	3 / 123	4 / 136	1 / 140
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac flutter			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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 hypertrophy			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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 perforation			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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 sarcoidosis			

subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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 tamponade			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac valve disease			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Cardiac ventricular thrombosis			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	1 / 2345 (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
Cardio-respiratory arrest			
subjects affected / exposed	24 / 2347 (1.02%)	24 / 2348 (1.02%)	20 / 2345 (0.85%)
occurrences causally related to treatment / all	1 / 24	3 / 24	0 / 20
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiogenic shock			
subjects affected / exposed	31 / 2347 (1.32%)	49 / 2348 (2.09%)	38 / 2345 (1.62%)
occurrences causally related to treatment / all	1 / 32	2 / 52	0 / 44
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiomegaly			
subjects affected / exposed	0 / 2347 (0.00%)	2 / 2348 (0.09%)	0 / 2345 (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
Cardiomyopathy			
subjects affected / exposed	2 / 2347 (0.09%)	2 / 2348 (0.09%)	4 / 2345 (0.17%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiopulmonary failure			

subjects affected / exposed	4 / 2347 (0.17%)	6 / 2348 (0.26%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 4	0 / 6	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiorenal syndrome			
subjects affected / exposed	2 / 2347 (0.09%)	0 / 2348 (0.00%)	1 / 2345 (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
Cardiovascular disorder			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiovascular insufficiency			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	1 / 2345 (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
Chordae tendinae rupture			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Chronotropic incompetence			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	1 / 2345 (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
Congestive cardiomyopathy			
subjects affected / exposed	14 / 2347 (0.60%)	14 / 2348 (0.60%)	19 / 2345 (0.81%)
occurrences causally related to treatment / all	0 / 15	0 / 14	0 / 22
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			
subjects affected / exposed	28 / 2347 (1.19%)	27 / 2348 (1.15%)	22 / 2345 (0.94%)
occurrences causally related to treatment / all	0 / 31	1 / 29	0 / 25
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery insufficiency			

subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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 artery occlusion			
subjects affected / exposed	0 / 2347 (0.00%)	2 / 2348 (0.09%)	1 / 2345 (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
Coronary artery stenosis			
subjects affected / exposed	8 / 2347 (0.34%)	5 / 2348 (0.21%)	8 / 2345 (0.34%)
occurrences causally related to treatment / all	0 / 8	0 / 7	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery thrombosis			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Extrasystoles			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Heart valve incompetence			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Hypertensive heart disease			
subjects affected / exposed	0 / 2347 (0.00%)	2 / 2348 (0.09%)	1 / 2345 (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
Ischaemic cardiomyopathy			
subjects affected / exposed	13 / 2347 (0.55%)	7 / 2348 (0.30%)	13 / 2345 (0.55%)
occurrences causally related to treatment / all	0 / 13	0 / 8	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Left ventricular dysfunction			

subjects affected / exposed	6 / 2347 (0.26%)	6 / 2348 (0.26%)	8 / 2345 (0.34%)
occurrences causally related to treatment / all	0 / 7	0 / 6	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Left ventricular failure			
subjects affected / exposed	6 / 2347 (0.26%)	5 / 2348 (0.21%)	6 / 2345 (0.26%)
occurrences causally related to treatment / all	0 / 7	0 / 7	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic cardiomyopathy			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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 incompetence			
subjects affected / exposed	6 / 2347 (0.26%)	17 / 2348 (0.72%)	14 / 2345 (0.60%)
occurrences causally related to treatment / all	0 / 6	0 / 19	0 / 17
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mitral valve prolapse			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Myocardial infarction			
subjects affected / exposed	56 / 2347 (2.39%)	50 / 2348 (2.13%)	50 / 2345 (2.13%)
occurrences causally related to treatment / all	1 / 63	0 / 51	0 / 57
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial ischaemia			
subjects affected / exposed	19 / 2347 (0.81%)	19 / 2348 (0.81%)	18 / 2345 (0.77%)
occurrences causally related to treatment / all	0 / 20	1 / 19	0 / 21
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nodal rhythm			

subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	0 / 2345 (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
Palpitations			
subjects affected / exposed	2 / 2347 (0.09%)	1 / 2348 (0.04%)	1 / 2345 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Papillary muscle rupture			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Pericardial effusion			
subjects affected / exposed	0 / 2347 (0.00%)	3 / 2348 (0.13%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	1 / 2345 (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
Pulmonary valve incompetence			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Pulseless electrical activity			
subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	3 / 2345 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Restrictive cardiomyopathy			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Rhythm idioventricular			



subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Right ventricular failure			
subjects affected / exposed	2 / 2347 (0.09%)	1 / 2348 (0.04%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	1 / 2	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinoatrial block			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	1 / 2345 (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
Sinus arrhythmia			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Sinus bradycardia			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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 node dysfunction			
subjects affected / exposed	6 / 2347 (0.26%)	3 / 2348 (0.13%)	5 / 2345 (0.21%)
occurrences causally related to treatment / all	0 / 6	1 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular extrasystoles			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Supraventricular tachyarrhythmia			
subjects affected / exposed	2 / 2347 (0.09%)	0 / 2348 (0.00%)	0 / 2345 (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
Supraventricular tachycardia			

subjects affected / exposed	7 / 2347 (0.30%)	5 / 2348 (0.21%)	3 / 2345 (0.13%)
occurrences causally related to treatment / all	0 / 7	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systolic dysfunction			
subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	0 / 2345 (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
Tachyarrhythmia			
subjects affected / exposed	0 / 2347 (0.00%)	2 / 2348 (0.09%)	0 / 2345 (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
Tachycardia			
subjects affected / exposed	9 / 2347 (0.38%)	5 / 2348 (0.21%)	4 / 2345 (0.17%)
occurrences causally related to treatment / all	1 / 10	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia paroxysmal			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Tricuspid valve disease			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Tricuspid valve incompetence			
subjects affected / exposed	1 / 2347 (0.04%)	3 / 2348 (0.13%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular arrhythmia			
subjects affected / exposed	14 / 2347 (0.60%)	8 / 2348 (0.34%)	14 / 2345 (0.60%)
occurrences causally related to treatment / all	0 / 16	0 / 8	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular dysfunction			

subjects affected / exposed	0 / 2347 (0.00%)	2 / 2348 (0.09%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular dyssynchrony			
subjects affected / exposed	2 / 2347 (0.09%)	0 / 2348 (0.00%)	0 / 2345 (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
Ventricular extrasystoles			
subjects affected / exposed	8 / 2347 (0.34%)	9 / 2348 (0.38%)	3 / 2345 (0.13%)
occurrences causally related to treatment / all	1 / 8	0 / 9	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular failure			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Ventricular fibrillation			
subjects affected / exposed	32 / 2347 (1.36%)	30 / 2348 (1.28%)	34 / 2345 (1.45%)
occurrences causally related to treatment / all	2 / 33	2 / 33	1 / 37
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular flutter			
subjects affected / exposed	2 / 2347 (0.09%)	2 / 2348 (0.09%)	0 / 2345 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular tachyarrhythmia			
subjects affected / exposed	2 / 2347 (0.09%)	0 / 2348 (0.00%)	1 / 2345 (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
Ventricular tachycardia			
subjects affected / exposed	78 / 2347 (3.32%)	67 / 2348 (2.85%)	63 / 2345 (2.69%)
occurrences causally related to treatment / all	2 / 97	2 / 92	0 / 75
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Ageusia			

subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Altered state of consciousness			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	1 / 2345 (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
Amyotrophic lateral sclerosis			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Aphasia			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Atonic seizures			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Balance disorder			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Basilar artery stenosis			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Brain hypoxia			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Brain injury			

subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	1 / 2345 (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
Brain oedema			
subjects affected / exposed	0 / 2347 (0.00%)	2 / 2348 (0.09%)	0 / 2345 (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
Brain stem infarction			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Brain stem syndrome			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Carotid arteriosclerosis			
subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	0 / 2345 (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
Carotid artery disease			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Carotid artery stenosis			
subjects affected / exposed	3 / 2347 (0.13%)	5 / 2348 (0.21%)	0 / 2345 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carpal tunnel syndrome			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Cerebellar ataxia			

subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	0 / 2345 (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
Cerebellar haemorrhage			
subjects affected / exposed	0 / 2347 (0.00%)	2 / 2348 (0.09%)	0 / 2345 (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
Cerebellar infarction			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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 amyloid angiopathy			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Cerebral arteriosclerosis			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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 artery embolism			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	5 / 2345 (0.21%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral artery occlusion			
subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	0 / 2345 (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
Cerebral atrophy			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral haematoma			

subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	0 / 2345 (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
Cerebral haemorrhage			
subjects affected / exposed	6 / 2347 (0.26%)	9 / 2348 (0.38%)	7 / 2345 (0.30%)
occurrences causally related to treatment / all	0 / 6	0 / 9	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral infarction			
subjects affected / exposed	9 / 2347 (0.38%)	17 / 2348 (0.72%)	17 / 2345 (0.72%)
occurrences causally related to treatment / all	0 / 10	1 / 17	0 / 18
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral ischaemia			
subjects affected / exposed	3 / 2347 (0.13%)	2 / 2348 (0.09%)	3 / 2345 (0.13%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	44 / 2347 (1.87%)	51 / 2348 (2.17%)	62 / 2345 (2.64%)
occurrences causally related to treatment / all	1 / 48	0 / 53	2 / 69
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular disorder			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	1 / 2345 (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
Cerebrovascular insufficiency			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Cervicogenic headache			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Cognitive disorder			

subjects affected / exposed	1 / 2347 (0.04%)	2 / 2348 (0.09%)	1 / 2345 (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
Coma			
subjects affected / exposed	1 / 2347 (0.04%)	3 / 2348 (0.13%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Complex partial seizures			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	1 / 2345 (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			
subjects affected / exposed	6 / 2347 (0.26%)	1 / 2348 (0.04%)	3 / 2345 (0.13%)
occurrences causally related to treatment / all	0 / 6	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depressed level of consciousness			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	1 / 2345 (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
Diabetic coma			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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 hyperosmolar coma			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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	2 / 2347 (0.09%)	1 / 2348 (0.04%)	0 / 2345 (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
Dizziness			



subjects affected / exposed	11 / 2347 (0.47%)	9 / 2348 (0.38%)	4 / 2345 (0.17%)
occurrences causally related to treatment / all	1 / 11	0 / 10	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness postural			
subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	0 / 2345 (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
Dysarthria			
subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	3 / 2345 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyslalia			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Embolitic cerebral infarction			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Embolitic stroke			
subjects affected / exposed	3 / 2347 (0.13%)	1 / 2348 (0.04%)	1 / 2345 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalomalacia			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Encephalopathy			
subjects affected / exposed	1 / 2347 (0.04%)	2 / 2348 (0.09%)	1 / 2345 (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
Epilepsy			

subjects affected / exposed	2 / 2347 (0.09%)	7 / 2348 (0.30%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 3	0 / 7	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Generalised tonic-clonic seizure			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Haemorrhage intracranial			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Haemorrhagic stroke			
subjects affected / exposed	3 / 2347 (0.13%)	4 / 2348 (0.17%)	4 / 2345 (0.17%)
occurrences causally related to treatment / all	0 / 3	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	1 / 2347 (0.04%)	3 / 2348 (0.13%)	1 / 2345 (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
Hemianopia			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Hemianopia homonymous			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Hemiparesis			
subjects affected / exposed	3 / 2347 (0.13%)	3 / 2348 (0.13%)	1 / 2345 (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
Hemiplegia			

subjects affected / exposed	0 / 2347 (0.00%)	2 / 2348 (0.09%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic encephalopathy			
subjects affected / exposed	0 / 2347 (0.00%)	2 / 2348 (0.09%)	0 / 2345 (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
Hydrocephalus			
subjects affected / exposed	2 / 2347 (0.09%)	0 / 2348 (0.00%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemic coma			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemic seizure			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Hypoxic-ischaemic encephalopathy			
subjects affected / exposed	2 / 2347 (0.09%)	2 / 2348 (0.09%)	3 / 2345 (0.13%)
occurrences causally related to treatment / all	0 / 2	1 / 2	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
IIIrd nerve paresis			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Intracranial aneurysm			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intraventricular haemorrhage			

subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Ischaemic cerebral infarction			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Ischaemic stroke			
subjects affected / exposed	45 / 2347 (1.92%)	45 / 2348 (1.92%)	29 / 2345 (1.24%)
occurrences causally related to treatment / all	1 / 47	0 / 51	0 / 30
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lacunar infarction			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	1 / 2345 (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
Leukoencephalopathy			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Loss of consciousness			
subjects affected / exposed	5 / 2347 (0.21%)	3 / 2348 (0.13%)	5 / 2345 (0.21%)
occurrences causally related to treatment / all	0 / 5	1 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental retardation			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Metabolic encephalopathy			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Monoparesis			

subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	1 / 2345 (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
Monoplegia			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Motor neurone disease			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Myelopathy			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Myoclonus			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Narcolepsy			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Nervous system disorder			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orthostatic intolerance			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Paraesthesia			

subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Paraparesis			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Paresis cranial nerve			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Parkinson's disease			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parkinsonism			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	1 / 2345 (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
Partial seizures			
subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	0 / 2345 (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
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Postresuscitation encephalopathy			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Presyncope			

subjects affected / exposed	4 / 2347 (0.17%)	5 / 2348 (0.21%)	9 / 2345 (0.38%)
occurrences causally related to treatment / all	1 / 4	0 / 5	1 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychomotor hyperactivity			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Radiculopathy			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Restless legs syndrome			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Retrograde amnesia			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Reversible ischaemic neurological deficit			
subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	0 / 2345 (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
Sciatica			
subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	0 / 2345 (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
Seizure			
subjects affected / exposed	1 / 2347 (0.04%)	4 / 2348 (0.17%)	0 / 2345 (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
Somnolence			

subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Spinal claudication			
subjects affected / exposed	0 / 2347 (0.00%)	2 / 2348 (0.09%)	0 / 2345 (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
Spinal epidural haematoma			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Subarachnoid haemorrhage			
subjects affected / exposed	3 / 2347 (0.13%)	1 / 2348 (0.04%)	3 / 2345 (0.13%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	48 / 2347 (2.05%)	56 / 2348 (2.39%)	27 / 2345 (1.15%)
occurrences causally related to treatment / all	5 / 58	7 / 71	1 / 31
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tension headache			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Thalamus haemorrhage			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Transient global amnesia			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Transient ischaemic attack			



subjects affected / exposed	23 / 2347 (0.98%)	20 / 2348 (0.85%)	15 / 2345 (0.64%)
occurrences causally related to treatment / all	0 / 23	0 / 20	1 / 18
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tremor			
subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	0 / 2345 (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
Trigeminal nerve disorder			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Uraemic encephalopathy			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
VIIth nerve paralysis			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular dementia			
subjects affected / exposed	0 / 2347 (0.00%)	2 / 2348 (0.09%)	1 / 2345 (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
Vascular encephalopathy			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	1 / 2345 (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
Vertebrobasilar insufficiency			
subjects affected / exposed	3 / 2347 (0.13%)	2 / 2348 (0.09%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	1 / 3	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Acquired haemophilia			

subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Anaemia			
subjects affected / exposed	36 / 2347 (1.53%)	28 / 2348 (1.19%)	28 / 2345 (1.19%)
occurrences causally related to treatment / all	2 / 39	0 / 40	1 / 31
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia vitamin B12 deficiency			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Aplastic anaemia			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Bicytopenia			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Bone marrow infiltration			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Coagulopathy			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Disseminated intravascular coagulation			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			

subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Haemolytic anaemia			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Haemorrhagic anaemia			
subjects affected / exposed	0 / 2347 (0.00%)	2 / 2348 (0.09%)	0 / 2345 (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
Haemorrhagic diathesis			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Hypochromic anaemia			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Hypocoagulable state			
subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	0 / 2345 (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
Iron deficiency anaemia			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	3 / 2345 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaundice acholuric			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Leukocytosis			

subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	0 / 2345 (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
Leukopenia			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Lymphadenitis			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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 mediastinal			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Microcytic anaemia			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Normochromic normocytic anaemia			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Pancytopenia			
subjects affected / exposed	4 / 2347 (0.17%)	2 / 2348 (0.09%)	0 / 2345 (0.00%)
occurrences causally related to treatment / all	1 / 7	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polycythaemia			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	1 / 2345 (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
Retroperitoneal lymphadenopathy			

subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Splenic embolism			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Splenic infarction			
subjects affected / exposed	0 / 2347 (0.00%)	2 / 2348 (0.09%)	0 / 2345 (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
Splenic vein thrombosis			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Thrombocytopenia			
subjects affected / exposed	3 / 2347 (0.13%)	1 / 2348 (0.04%)	3 / 2345 (0.13%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Deafness neurosensory			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Deafness unilateral			
subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	1 / 2345 (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
Haematotympanum			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Meniere's disease			

subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Sudden hearing loss			
subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	0 / 2345 (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
Tympanic membrane perforation			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Vertigo			
subjects affected / exposed	2 / 2347 (0.09%)	3 / 2348 (0.13%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 2	1 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertigo positional			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Eye disorders			
Amaurosis fugax			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Amblyopia			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Cataract			
subjects affected / exposed	13 / 2347 (0.55%)	8 / 2348 (0.34%)	6 / 2345 (0.26%)
occurrences causally related to treatment / all	0 / 16	0 / 9	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Conjunctival haemorrhage			

subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	1 / 2345 (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
Diabetic retinopathy			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	1 / 2345 (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
Glaucoma			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	1 / 2345 (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
Macular hole			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	1 / 2345 (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
Ocular fistula			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Ocular retrobulbar haemorrhage			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Ophthalmic vein thrombosis			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Retinal artery embolism			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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 degeneration			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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 detachment			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal haemorrhage			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Retinal vein occlusion			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Retinopathy			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Visual acuity reduced			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Vitreous haemorrhage			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Gastrointestinal disorders			
Abdominal adhesions			



subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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 discomfort			
subjects affected / exposed	1 / 2347 (0.04%)	2 / 2348 (0.09%)	0 / 2345 (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
Abdominal distension			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal hernia			
subjects affected / exposed	3 / 2347 (0.13%)	1 / 2348 (0.04%)	0 / 2345 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	14 / 2347 (0.60%)	10 / 2348 (0.43%)	11 / 2345 (0.47%)
occurrences causally related to treatment / all	0 / 16	0 / 23	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain lower			
subjects affected / exposed	2 / 2347 (0.09%)	0 / 2348 (0.00%)	0 / 2345 (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
Abdominal pain upper			
subjects affected / exposed	4 / 2347 (0.17%)	5 / 2348 (0.21%)	4 / 2345 (0.17%)
occurrences causally related to treatment / all	0 / 7	0 / 6	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal strangulated hernia			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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 wall haematoma			

subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Acid peptic disease			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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	1 / 2347 (0.04%)	1 / 2348 (0.04%)	1 / 2345 (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
Alcoholic pancreatitis			
subjects affected / exposed	0 / 2347 (0.00%)	2 / 2348 (0.09%)	0 / 2345 (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
Anal fissure			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	1 / 2345 (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 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Anal prolapse			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Ascites			
subjects affected / exposed	6 / 2347 (0.26%)	6 / 2348 (0.26%)	6 / 2345 (0.26%)
occurrences causally related to treatment / all	0 / 13	0 / 6	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Autoimmune pancreatitis			

subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Chronic gastritis			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	1 / 2345 (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
Colitis			
subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	3 / 2345 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis ischaemic			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis ulcerative			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Constipation			
subjects affected / exposed	6 / 2347 (0.26%)	5 / 2348 (0.21%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	1 / 7	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Crohn's disease			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Dental caries			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Diabetic gastroparesis			

subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Diarrhoea			
subjects affected / exposed	18 / 2347 (0.77%)	4 / 2348 (0.17%)	11 / 2345 (0.47%)
occurrences causally related to treatment / all	1 / 20	0 / 4	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dieulafoy's vascular malformation			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Diverticular perforation			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Diverticulum			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	1 / 2345 (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
Diverticulum intestinal			
subjects affected / exposed	0 / 2347 (0.00%)	2 / 2348 (0.09%)	1 / 2345 (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
Diverticulum intestinal haemorrhagic			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Duodenal ulcer			
subjects affected / exposed	1 / 2347 (0.04%)	2 / 2348 (0.09%)	5 / 2345 (0.21%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal ulcer haemorrhage			

subjects affected / exposed	3 / 2347 (0.13%)	0 / 2348 (0.00%)	1 / 2345 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal ulcer perforation			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenitis			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	1 / 2345 (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
Dyspepsia			
subjects affected / exposed	4 / 2347 (0.17%)	2 / 2348 (0.09%)	0 / 2345 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	3 / 2347 (0.13%)	0 / 2348 (0.00%)	1 / 2345 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	1 / 2345 (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
Enterocolitis			
subjects affected / exposed	3 / 2347 (0.13%)	1 / 2348 (0.04%)	0 / 2345 (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
Enterovesical fistula			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Eosinophilic oesophagitis			

subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Epigastric discomfort			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Erosive duodenitis			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Erosive oesophagitis			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Faecaloma			
subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	0 / 2345 (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
Femoral hernia			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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 hernia, obstructive			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Gastric haemorrhage			
subjects affected / exposed	0 / 2347 (0.00%)	2 / 2348 (0.09%)	3 / 2345 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric polyps			

subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	0 / 2345 (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
Gastric ulcer			
subjects affected / exposed	7 / 2347 (0.30%)	4 / 2348 (0.17%)	8 / 2345 (0.34%)
occurrences causally related to treatment / all	0 / 7	0 / 4	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric ulcer haemorrhage			
subjects affected / exposed	6 / 2347 (0.26%)	2 / 2348 (0.09%)	5 / 2345 (0.21%)
occurrences causally related to treatment / all	0 / 6	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric ulcer perforation			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Gastritis			
subjects affected / exposed	10 / 2347 (0.43%)	4 / 2348 (0.17%)	4 / 2345 (0.17%)
occurrences causally related to treatment / all	0 / 10	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis erosive			
subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	3 / 2345 (0.13%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis haemorrhagic			
subjects affected / exposed	2 / 2347 (0.09%)	0 / 2348 (0.00%)	1 / 2345 (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
Gastroduodenal ulcer			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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 angiodysplasia			

subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	1 / 2345 (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
Gastrointestinal haemorrhage			
subjects affected / exposed	19 / 2347 (0.81%)	13 / 2348 (0.55%)	11 / 2345 (0.47%)
occurrences causally related to treatment / all	0 / 19	1 / 14	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal inflammation			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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 ischaemia			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Gastrointestinal necrosis			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	4 / 2345 (0.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal polyp haemorrhage			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal ulcer			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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	2 / 2347 (0.09%)	2 / 2348 (0.09%)	4 / 2345 (0.17%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gingival bleeding			



subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Haematemesis			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematochezia			
subjects affected / exposed	2 / 2347 (0.09%)	0 / 2348 (0.00%)	1 / 2345 (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
Haemorrhagic erosive gastritis			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Haemorrhoidal haemorrhage			
subjects affected / exposed	1 / 2347 (0.04%)	4 / 2348 (0.17%)	1 / 2345 (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
Haemorrhoids			
subjects affected / exposed	0 / 2347 (0.00%)	5 / 2348 (0.21%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hiatus hernia			
subjects affected / exposed	0 / 2347 (0.00%)	2 / 2348 (0.09%)	0 / 2345 (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
Ileus			
subjects affected / exposed	4 / 2347 (0.17%)	3 / 2348 (0.13%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 5	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus paralytic			

subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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 inguinal hernia			
subjects affected / exposed	2 / 2347 (0.09%)	2 / 2348 (0.09%)	0 / 2345 (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
Incarcerated umbilical hernia			
subjects affected / exposed	1 / 2347 (0.04%)	2 / 2348 (0.09%)	0 / 2345 (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
Inguinal hernia			
subjects affected / exposed	23 / 2347 (0.98%)	21 / 2348 (0.89%)	14 / 2345 (0.60%)
occurrences causally related to treatment / all	1 / 23	0 / 21	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal fistula			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Intestinal haemorrhage			
subjects affected / exposed	1 / 2347 (0.04%)	2 / 2348 (0.09%)	0 / 2345 (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
Intestinal infarction			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Intestinal ischaemia			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	4 / 2345 (0.17%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			

subjects affected / exposed	2 / 2347 (0.09%)	3 / 2348 (0.13%)	3 / 2345 (0.13%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal perforation			
subjects affected / exposed	0 / 2347 (0.00%)	2 / 2348 (0.09%)	0 / 2345 (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
Intestinal polyp			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	3 / 2345 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal strangulation			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Irritable bowel syndrome			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal stenosis			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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	2 / 2347 (0.09%)	5 / 2348 (0.21%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 2	0 / 5	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower gastrointestinal haemorrhage			

subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	4 / 2345 (0.17%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mallory-Weiss syndrome			
subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	0 / 2345 (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
Melaena			
subjects affected / exposed	3 / 2347 (0.13%)	4 / 2348 (0.17%)	4 / 2345 (0.17%)
occurrences causally related to treatment / all	0 / 3	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mesenteric artery embolism			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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	2 / 2347 (0.09%)	0 / 2348 (0.00%)	0 / 2345 (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
Mesenteritis			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Mouth haemorrhage			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Nausea			
subjects affected / exposed	5 / 2347 (0.21%)	4 / 2348 (0.17%)	3 / 2345 (0.13%)
occurrences causally related to treatment / all	0 / 6	0 / 4	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstruction gastric			

subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Oedematous pancreatitis			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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 haemorrhage			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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 ulcer			
subjects affected / exposed	1 / 2347 (0.04%)	2 / 2348 (0.09%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 1	1 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal ulcer haemorrhage			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Oesophagitis			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	1 / 2345 (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
Oesophagitis haemorrhagic			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Pancreatic cyst			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	1 / 2345 (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
Pancreatitis			

subjects affected / exposed	5 / 2347 (0.21%)	4 / 2348 (0.17%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 5	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis acute			
subjects affected / exposed	9 / 2347 (0.38%)	5 / 2348 (0.21%)	5 / 2345 (0.21%)
occurrences causally related to treatment / all	1 / 9	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis chronic			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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 necrotising			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Peptic ulcer			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Peptic ulcer haemorrhage			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Peptic ulcer perforation			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Pharyngo-oesophageal diverticulum			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Portal hypertensive gastropathy			

subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Proctalgia			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Proctitis			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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	7 / 2347 (0.30%)	5 / 2348 (0.21%)	3 / 2345 (0.13%)
occurrences causally related to treatment / all	0 / 8	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal polyp			
subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	1 / 2345 (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
Rectal prolapse			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Small intestinal obstruction			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	1 / 2345 (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
Stress ulcer			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Subileus			

subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	0 / 2345 (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
Thrombosis mesenteric vessel			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Tongue oedema			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Tooth disorder			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Umbilical hernia			
subjects affected / exposed	5 / 2347 (0.21%)	5 / 2348 (0.21%)	1 / 2345 (0.04%)
occurrences causally related to treatment / all	0 / 6	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	6 / 2347 (0.26%)	12 / 2348 (0.51%)	7 / 2345 (0.30%)
occurrences causally related to treatment / all	0 / 6	1 / 12	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Visceral congestion			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Volvulus			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	1 / 2345 (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
Volvulus of small bowel			



subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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	5 / 2347 (0.21%)	5 / 2348 (0.21%)	4 / 2345 (0.17%)
occurrences causally related to treatment / all	0 / 6	0 / 6	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Acquired epidermolysis bullosa			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Actinic keratosis			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Angioedema			
subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	0 / 2345 (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
Decubitus ulcer			
subjects affected / exposed	3 / 2347 (0.13%)	1 / 2348 (0.04%)	1 / 2345 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermal cyst			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Dermatitis			
subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	0 / 2345 (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
Dermatitis allergic			

subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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>Dermatitis bullous</b>			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
<b>Dermatitis contact</b>			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
<b>Diabetic foot</b>			
subjects affected / exposed	5 / 2347 (0.21%)	1 / 2348 (0.04%)	0 / 2345 (0.00%)
occurrences causally related to treatment / all	0 / 7	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Diabetic ulcer</b>			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
<b>Drug eruption</b>			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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>Ecchymosis</b>			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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>Erythema</b>			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
<b>Fungating wound</b>			

subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Henoch-Schonlein purpura			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Hyperhidrosis			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Intertrigo			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Lichen sclerosus			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Neuropathic ulcer			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Peau d'orange			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Precancerous skin lesion			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Pruritus			

subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Psoriasis			
subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	0 / 2345 (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
Purpura			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Rash			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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 necrosis			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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	4 / 2347 (0.17%)	4 / 2348 (0.17%)	4 / 2345 (0.17%)
occurrences causally related to treatment / all	0 / 4	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin ulcer haemorrhage			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Toxic skin eruption			

subjects affected / exposed	2 / 2347 (0.09%)	0 / 2348 (0.00%)	0 / 2345 (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
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	52 / 2347 (2.22%)	29 / 2348 (1.24%)	38 / 2345 (1.62%)
occurrences causally related to treatment / all	12 / 60	5 / 31	1 / 41
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute prerenal failure			
subjects affected / exposed	1 / 2347 (0.04%)	2 / 2348 (0.09%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	1 / 1	2 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anuria			
subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	1 / 2345 (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
Azotaemia			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Calculus bladder			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus ureteric			
subjects affected / exposed	1 / 2347 (0.04%)	2 / 2348 (0.09%)	1 / 2345 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus urethral			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Calculus urinary			

subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Chronic kidney disease			
subjects affected / exposed	21 / 2347 (0.89%)	10 / 2348 (0.43%)	10 / 2345 (0.43%)
occurrences causally related to treatment / all	6 / 24	0 / 10	3 / 12
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic nephropathy			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Dysuria			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	1 / 2345 (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
Glomerulonephritis membranous			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Haematuria			
subjects affected / exposed	4 / 2347 (0.17%)	6 / 2348 (0.26%)	5 / 2345 (0.21%)
occurrences causally related to treatment / all	0 / 4	0 / 6	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Hypertensive nephropathy			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Ischaemic nephropathy			

subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	0 / 2345 (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
<b>Nephritis</b>			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
<b>Nephrolithiasis</b>			
subjects affected / exposed	3 / 2347 (0.13%)	1 / 2348 (0.04%)	1 / 2345 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Nephropathy</b>			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
<b>Nephrotic syndrome</b>			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	1 / 2345 (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
<b>Polyuria</b>			
subjects affected / exposed	2 / 2347 (0.09%)	1 / 2348 (0.04%)	0 / 2345 (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
<b>Postrenal failure</b>			
subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	0 / 2345 (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
<b>Prerenal failure</b>			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
<b>Proteinuria</b>			

subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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 cyst			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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 disorder			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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 embolism			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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 failure			
subjects affected / exposed	33 / 2347 (1.41%)	26 / 2348 (1.11%)	27 / 2345 (1.15%)
occurrences causally related to treatment / all	6 / 34	4 / 26	4 / 29
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal impairment			
subjects affected / exposed	34 / 2347 (1.45%)	31 / 2348 (1.32%)	33 / 2345 (1.41%)
occurrences causally related to treatment / all	9 / 36	8 / 33	8 / 33
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal infarct			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal tubular necrosis			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Ureteric fistula			



subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Ureteric stenosis			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Urethral obstruction			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Urethral stenosis			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary bladder haemorrhage			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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 bladder polyp			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	1 / 2345 (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
Urinary retention			
subjects affected / exposed	3 / 2347 (0.13%)	7 / 2348 (0.30%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 3	1 / 9	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract obstruction			
subjects affected / exposed	0 / 2347 (0.00%)	2 / 2348 (0.09%)	0 / 2345 (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
Urinoma			

subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Endocrine disorders			
Goitre			
subjects affected / exposed	2 / 2347 (0.09%)	1 / 2348 (0.04%)	0 / 2345 (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
Hyperthyroidism			
subjects affected / exposed	2 / 2347 (0.09%)	5 / 2348 (0.21%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 2	1 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypothyroidism			
subjects affected / exposed	2 / 2347 (0.09%)	7 / 2348 (0.30%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 2	0 / 7	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thyrotoxic crisis			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Toxic nodular goitre			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	6 / 2347 (0.26%)	3 / 2348 (0.13%)	4 / 2345 (0.17%)
occurrences causally related to treatment / all	0 / 7	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis			
subjects affected / exposed	2 / 2347 (0.09%)	2 / 2348 (0.09%)	3 / 2345 (0.13%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Back pain			
subjects affected / exposed	4 / 2347 (0.17%)	4 / 2348 (0.17%)	3 / 2345 (0.13%)
occurrences causally related to treatment / all	0 / 4	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bursitis			
subjects affected / exposed	0 / 2347 (0.00%)	3 / 2348 (0.13%)	0 / 2345 (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
Cervical spinal stenosis			
subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	0 / 2345 (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
Chondropathy			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Compartment syndrome			
subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	0 / 2345 (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
Connective tissue inflammation			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Costochondritis			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Diabetic amyotrophy			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Fistula			

subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Flank pain			
subjects affected / exposed	1 / 2347 (0.04%)	2 / 2348 (0.09%)	0 / 2345 (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
Foot deformity			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Fracture malunion			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Gouty arthritis			
subjects affected / exposed	6 / 2347 (0.26%)	3 / 2348 (0.13%)	1 / 2345 (0.04%)
occurrences causally related to treatment / all	0 / 7	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemarthrosis			
subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc degeneration			
subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	0 / 2345 (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
Intervertebral disc protrusion			
subjects affected / exposed	1 / 2347 (0.04%)	3 / 2348 (0.13%)	3 / 2345 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint effusion			

subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Joint instability			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Lumbar spinal stenosis			
subjects affected / exposed	2 / 2347 (0.09%)	3 / 2348 (0.13%)	1 / 2345 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle atrophy			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Muscle haemorrhage			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			
subjects affected / exposed	0 / 2347 (0.00%)	5 / 2348 (0.21%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal chest pain			
subjects affected / exposed	3 / 2347 (0.13%)	2 / 2348 (0.09%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal pain			
subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal stiffness			

subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Myalgia			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	3 / 2345 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myopathy			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Myopathy toxic			
subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	0 / 2345 (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
Myositis			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Neck pain			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Osteitis			
subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	0 / 2345 (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
Osteoarthritis			
subjects affected / exposed	9 / 2347 (0.38%)	12 / 2348 (0.51%)	10 / 2345 (0.43%)
occurrences causally related to treatment / all	0 / 9	0 / 15	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteochondritis			

subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Osteochondrosis			
subjects affected / exposed	2 / 2347 (0.09%)	1 / 2348 (0.04%)	1 / 2345 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteonecrosis			
subjects affected / exposed	2 / 2347 (0.09%)	0 / 2348 (0.00%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteonecrosis of jaw			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Osteoporosis			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	1 / 2345 (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
Osteoporotic fracture			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	1 / 2345 (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
Pain in extremity			
subjects affected / exposed	4 / 2347 (0.17%)	3 / 2348 (0.13%)	6 / 2345 (0.26%)
occurrences causally related to treatment / all	0 / 5	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pathological fracture			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Polyarthrititis			

subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Rhabdomyolysis			
subjects affected / exposed	2 / 2347 (0.09%)	0 / 2348 (0.00%)	1 / 2345 (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
Rheumatic disorder			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Rheumatoid arthritis			
subjects affected / exposed	3 / 2347 (0.13%)	0 / 2348 (0.00%)	0 / 2345 (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
Rotator cuff syndrome			
subjects affected / exposed	0 / 2347 (0.00%)	4 / 2348 (0.17%)	0 / 2345 (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
Scleroderma			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Spinal column stenosis			
subjects affected / exposed	0 / 2347 (0.00%)	3 / 2348 (0.13%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal deformity			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Spinal osteoarthritis			



subjects affected / exposed	2 / 2347 (0.09%)	2 / 2348 (0.09%)	0 / 2345 (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
Spinal pain			
subjects affected / exposed	2 / 2347 (0.09%)	0 / 2348 (0.00%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Synovial cyst			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	1 / 2345 (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
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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 infection			
subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	0 / 2345 (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 sepsis			
subjects affected / exposed	3 / 2347 (0.13%)	2 / 2348 (0.09%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess intestinal			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Abscess jaw			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Abscess limb			

subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	4 / 2345 (0.17%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess oral			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Acinetobacter infection			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Anal abscess			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	3 / 2345 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendiceal abscess			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Appendicitis			
subjects affected / exposed	5 / 2347 (0.21%)	2 / 2348 (0.09%)	5 / 2345 (0.21%)
occurrences causally related to treatment / all	0 / 5	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis perforated			
subjects affected / exposed	2 / 2347 (0.09%)	2 / 2348 (0.09%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis bacterial			
subjects affected / exposed	1 / 2347 (0.04%)	3 / 2348 (0.13%)	1 / 2345 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis infective			

subjects affected / exposed	2 / 2347 (0.09%)	1 / 2348 (0.04%)	0 / 2345 (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
Atypical pneumonia			
subjects affected / exposed	0 / 2347 (0.00%)	2 / 2348 (0.09%)	1 / 2345 (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
Bacteraemia			
subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	1 / 2345 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial diarrhoea			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Bacterial infection			
subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	1 / 2345 (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
Bacterial sepsis			
subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary sepsis			
subjects affected / exposed	2 / 2347 (0.09%)	0 / 2348 (0.00%)	0 / 2345 (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
Bone abscess			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Bone tuberculosis			

subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Brain abscess			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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			
subjects affected / exposed	22 / 2347 (0.94%)	16 / 2348 (0.68%)	11 / 2345 (0.47%)
occurrences causally related to treatment / all	0 / 26	0 / 16	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis bacterial			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Bronchitis viral			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	1 / 2345 (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
Burn infection			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Bursitis infective			
subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	0 / 2345 (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
Campylobacter gastroenteritis			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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 valve abscess			

subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Cellulitis			
subjects affected / exposed	6 / 2347 (0.26%)	9 / 2348 (0.38%)	13 / 2345 (0.55%)
occurrences causally related to treatment / all	0 / 7	0 / 12	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis infective			
subjects affected / exposed	3 / 2347 (0.13%)	0 / 2348 (0.00%)	0 / 2345 (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
Chronic sinusitis			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Clostridial infection			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Clostridium difficile colitis			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			
subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	0 / 2345 (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
Corynebacterium infection			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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	6 / 2347 (0.26%)	1 / 2348 (0.04%)	3 / 2345 (0.13%)
occurrences causally related to treatment / all	0 / 6	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus infection			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Dengue fever			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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 related infection			
subjects affected / exposed	6 / 2347 (0.26%)	6 / 2348 (0.26%)	4 / 2345 (0.17%)
occurrences causally related to treatment / all	0 / 6	0 / 10	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related sepsis			
subjects affected / exposed	0 / 2347 (0.00%)	3 / 2348 (0.13%)	0 / 2345 (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
Diabetic foot infection			
subjects affected / exposed	3 / 2347 (0.13%)	0 / 2348 (0.00%)	1 / 2345 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea infectious			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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	6 / 2347 (0.26%)	0 / 2348 (0.00%)	4 / 2345 (0.17%)
occurrences causally related to treatment / all	0 / 6	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysentery			

subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Emphyema			
subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	0 / 2345 (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
Encephalitis			
subjects affected / exposed	1 / 2347 (0.04%)	2 / 2348 (0.09%)	0 / 2345 (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
Endocarditis			
subjects affected / exposed	5 / 2347 (0.21%)	5 / 2348 (0.21%)	4 / 2345 (0.17%)
occurrences causally related to treatment / all	0 / 5	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocarditis bacterial			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Endocarditis staphylococcal			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Enteritis infectious			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	1 / 2345 (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
Enterococcal sepsis			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Epididymitis			

subjects affected / exposed	1 / 2347 (0.04%)	2 / 2348 (0.09%)	0 / 2345 (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
Erysipelas			
subjects affected / exposed	6 / 2347 (0.26%)	7 / 2348 (0.30%)	10 / 2345 (0.43%)
occurrences causally related to treatment / all	0 / 6	0 / 7	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia infection			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Escherichia urinary tract infection			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Febrile infection			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Fungal oesophagitis			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Gangrene			
subjects affected / exposed	10 / 2347 (0.43%)	3 / 2348 (0.13%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 12	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric ulcer helicobacter			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Gastroenteritis			



subjects affected / exposed	13 / 2347 (0.55%)	10 / 2348 (0.43%)	16 / 2345 (0.68%)
occurrences causally related to treatment / all	0 / 13	1 / 10	0 / 17
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis clostridial			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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 norovirus			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal infection			
subjects affected / exposed	2 / 2347 (0.09%)	0 / 2348 (0.00%)	1 / 2345 (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
Genitourinary tract infection			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Groin abscess			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
H1N1 influenza			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Haematoma infection			

subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemophilus sepsis			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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 infection			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Hepatic infection bacterial			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Hepatitis B			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Hepatitis viral			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Herpes zoster			
subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	4 / 2345 (0.17%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster cutaneous disseminated			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Human ehrlichiosis			

subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Implant site infection			
subjects affected / exposed	3 / 2347 (0.13%)	1 / 2348 (0.04%)	3 / 2345 (0.13%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incision site abscess			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Incision site infection			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Infected cyst			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Infected seroma			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Infected skin ulcer			
subjects affected / exposed	2 / 2347 (0.09%)	4 / 2348 (0.17%)	3 / 2345 (0.13%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	4 / 2347 (0.17%)	2 / 2348 (0.09%)	4 / 2345 (0.17%)
occurrences causally related to treatment / all	0 / 4	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infectious colitis			

subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	1 / 2345 (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
Infectious pleural effusion			
subjects affected / exposed	1 / 2347 (0.04%)	2 / 2348 (0.09%)	0 / 2345 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	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 / 2347 (0.04%)	4 / 2348 (0.17%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	2 / 2347 (0.09%)	2 / 2348 (0.09%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral discitis			
subjects affected / exposed	2 / 2347 (0.09%)	0 / 2348 (0.00%)	0 / 2345 (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
Intestinal sepsis			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Klebsiella sepsis			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Laryngitis			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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 abscess			

subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	1 / 2345 (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
Localised infection			
subjects affected / exposed	5 / 2347 (0.21%)	4 / 2348 (0.17%)	3 / 2345 (0.13%)
occurrences causally related to treatment / all	0 / 7	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	5 / 2347 (0.21%)	6 / 2348 (0.26%)	9 / 2345 (0.38%)
occurrences causally related to treatment / all	0 / 6	0 / 7	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung abscess			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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 infection			
subjects affected / exposed	10 / 2347 (0.43%)	6 / 2348 (0.26%)	13 / 2345 (0.55%)
occurrences causally related to treatment / all	0 / 10	0 / 9	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lyme disease			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Mucormycosis			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Mycobacterial infection			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Myiasis			

subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Nasopharyngitis			
subjects affected / exposed	3 / 2347 (0.13%)	2 / 2348 (0.09%)	0 / 2345 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Necrotising fasciitis			
subjects affected / exposed	2 / 2347 (0.09%)	1 / 2348 (0.04%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ophthalmic herpes zoster			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Oral fungal infection			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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 infection			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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	2 / 2347 (0.09%)	1 / 2348 (0.04%)	1 / 2345 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oropharyngitis fungal			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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 / 2347 (0.00%)	0 / 2348 (0.00%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media acute			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Otitis media chronic			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	1 / 2345 (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
Parametritis			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Paronychia			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Periodontitis			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	1 / 2345 (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
Peritonitis			
subjects affected / exposed	2 / 2347 (0.09%)	3 / 2348 (0.13%)	6 / 2345 (0.26%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis bacterial			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Pneumococcal sepsis			

subjects affected / exposed	2 / 2347 (0.09%)	5 / 2348 (0.21%)	1 / 2345 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 6	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumocystis jirovecii infection			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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			
subjects affected / exposed	136 / 2347 (5.79%)	145 / 2348 (6.18%)	122 / 2345 (5.20%)
occurrences causally related to treatment / all	1 / 164	0 / 176	0 / 146
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia bacterial			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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 escherichia			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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 haemophilus			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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 influenzal			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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 mycoplasmal			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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 pneumococcal			



subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	0 / 2345 (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 pseudomonal			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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 staphylococcal			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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 viral			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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 procedural infection			
subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	1 / 2345 (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
Post procedural sepsis			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Postoperative wound infection			
subjects affected / exposed	0 / 2347 (0.00%)	2 / 2348 (0.09%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatic abscess			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Pseudomembranous colitis			

subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Pseudomonal sepsis			
subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	1 / 2345 (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
Pseudomonas infection			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	1 / 2345 (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
Psoas abscess			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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	8 / 2347 (0.34%)	6 / 2348 (0.26%)	4 / 2345 (0.17%)
occurrences causally related to treatment / all	0 / 8	0 / 6	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary tuberculosis			
subjects affected / exposed	0 / 2347 (0.00%)	2 / 2348 (0.09%)	0 / 2345 (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
Pyelonephritis			
subjects affected / exposed	4 / 2347 (0.17%)	3 / 2348 (0.13%)	1 / 2345 (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
Pyelonephritis acute			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	1 / 2345 (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
Pyelonephritis chronic			

subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Rectal abscess			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	8 / 2347 (0.34%)	15 / 2348 (0.64%)	19 / 2345 (0.81%)
occurrences causally related to treatment / all	1 / 8	0 / 19	0 / 20
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection bacterial			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	1 / 2345 (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
Respiratory tract infection fungal			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Respiratory tract infection viral			
subjects affected / exposed	1 / 2347 (0.04%)	2 / 2348 (0.09%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	14 / 2347 (0.60%)	18 / 2348 (0.77%)	12 / 2345 (0.51%)
occurrences causally related to treatment / all	0 / 15	0 / 19	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic necrosis			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Septic shock			

subjects affected / exposed	13 / 2347 (0.55%)	21 / 2348 (0.89%)	13 / 2345 (0.55%)
occurrences causally related to treatment / all	0 / 13	0 / 21	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sialoadenitis			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Sinusitis			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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 bacterial infection			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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 infection			
subjects affected / exposed	2 / 2347 (0.09%)	1 / 2348 (0.04%)	1 / 2345 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue infection			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Spinal cord infection			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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 bacteraemia			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Staphylococcal infection			

subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal sepsis			
subjects affected / exposed	0 / 2347 (0.00%)	2 / 2348 (0.09%)	3 / 2345 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Streptococcal endocarditis			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Streptococcal sepsis			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Subcutaneous abscess			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	3 / 2345 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombophlebitis septic			
subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	0 / 2345 (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
Tooth abscess			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tooth infection			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	1 / 2345 (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
Tracheitis			

subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	0 / 2345 (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
Tracheobronchitis			
subjects affected / exposed	6 / 2347 (0.26%)	5 / 2348 (0.21%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 8	1 / 7	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	4 / 2347 (0.17%)	5 / 2348 (0.21%)	6 / 2345 (0.26%)
occurrences causally related to treatment / all	0 / 4	0 / 5	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection bacterial			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Urethritis			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Urinary tract infection			
subjects affected / exposed	22 / 2347 (0.94%)	21 / 2348 (0.89%)	19 / 2345 (0.81%)
occurrences causally related to treatment / all	0 / 25	0 / 22	0 / 19
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection bacterial			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	1 / 2345 (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
Urinary tract infection pseudomonal			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Urosepsis			

subjects affected / exposed	5 / 2347 (0.21%)	7 / 2348 (0.30%)	3 / 2345 (0.13%)
occurrences causally related to treatment / all	0 / 5	0 / 7	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	0 / 2347 (0.00%)	3 / 2348 (0.13%)	0 / 2345 (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
Viral pericarditis			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Viral upper respiratory tract infection			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	1 / 2345 (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
Viral vasculitis			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Wound infection			
subjects affected / exposed	2 / 2347 (0.09%)	1 / 2348 (0.04%)	1 / 2345 (0.04%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection bacterial			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Wound infection staphylococcal			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Wound sepsis			

subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Metabolism and nutrition disorders			
Acidosis			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	3 / 2345 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cachexia			
subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	0 / 2345 (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
Carbohydrate intolerance			
subjects affected / exposed	0 / 2347 (0.00%)	2 / 2348 (0.09%)	1 / 2345 (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
Decreased appetite			
subjects affected / exposed	7 / 2347 (0.30%)	6 / 2348 (0.26%)	1 / 2345 (0.04%)
occurrences causally related to treatment / all	0 / 9	2 / 6	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
subjects affected / exposed	27 / 2347 (1.15%)	21 / 2348 (0.89%)	14 / 2345 (0.60%)
occurrences causally related to treatment / all	1 / 30	0 / 24	0 / 16
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes mellitus			
subjects affected / exposed	15 / 2347 (0.64%)	16 / 2348 (0.68%)	10 / 2345 (0.43%)
occurrences causally related to treatment / all	1 / 16	0 / 16	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes mellitus inadequate control			
subjects affected / exposed	7 / 2347 (0.30%)	6 / 2348 (0.26%)	4 / 2345 (0.17%)
occurrences causally related to treatment / all	0 / 7	0 / 6	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic ketoacidosis			



subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrolyte imbalance			
subjects affected / exposed	3 / 2347 (0.13%)	0 / 2348 (0.00%)	3 / 2345 (0.13%)
occurrences causally related to treatment / all	0 / 3	0 / 0	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fluid overload			
subjects affected / exposed	3 / 2347 (0.13%)	0 / 2348 (0.00%)	1 / 2345 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fluid retention			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Glucose tolerance impaired			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Gout			
subjects affected / exposed	11 / 2347 (0.47%)	11 / 2348 (0.47%)	5 / 2345 (0.21%)
occurrences causally related to treatment / all	0 / 13	1 / 14	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	2 / 2347 (0.09%)	1 / 2348 (0.04%)	0 / 2345 (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
Hyperglycaemia			
subjects affected / exposed	6 / 2347 (0.26%)	1 / 2348 (0.04%)	3 / 2345 (0.13%)
occurrences causally related to treatment / all	0 / 7	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkalaemia			

subjects affected / exposed	21 / 2347 (0.89%)	13 / 2348 (0.55%)	20 / 2345 (0.85%)
occurrences causally related to treatment / all	12 / 22	6 / 14	11 / 22
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperosmolar hyperglycaemic state			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Hyperosmolar state			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Hypertriglyceridaemia			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Hyperuricaemia			
subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	0 / 2345 (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
Hypervolaemia			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Hypoalbuminaemia			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Hypocalcaemia			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			

subjects affected / exposed	10 / 2347 (0.43%)	5 / 2348 (0.21%)	5 / 2345 (0.21%)
occurrences causally related to treatment / all	0 / 12	0 / 6	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	10 / 2347 (0.43%)	12 / 2348 (0.51%)	10 / 2345 (0.43%)
occurrences causally related to treatment / all	0 / 10	0 / 14	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypomagnesaemia			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	5 / 2347 (0.21%)	7 / 2348 (0.30%)	10 / 2345 (0.43%)
occurrences causally related to treatment / all	0 / 5	0 / 10	1 / 12
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypophagia			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Hypoproteinaemia			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypovolaemia			
subjects affected / exposed	0 / 2347 (0.00%)	2 / 2348 (0.09%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Insulin resistance			
subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Iron deficiency			

subjects affected / exposed	0 / 2347 (0.00%)	1 / 2348 (0.04%)	0 / 2345 (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
Ketoacidosis			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	1 / 2345 (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
Malnutrition			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Marasmus			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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	2 / 2347 (0.09%)	0 / 2348 (0.00%)	2 / 2345 (0.09%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic disorder			
subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Mineral deficiency			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Obesity			
subjects affected / exposed	1 / 2347 (0.04%)	0 / 2348 (0.00%)	0 / 2345 (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
Polydipsia			

subjects affected / exposed	0 / 2347 (0.00%)	0 / 2348 (0.00%)	1 / 2345 (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
Type 1 diabetes mellitus			
subjects affected / exposed	1 / 2347 (0.04%)	1 / 2348 (0.04%)	1 / 2345 (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
Type 2 diabetes mellitus			
subjects affected / exposed	12 / 2347 (0.51%)	10 / 2348 (0.43%)	8 / 2345 (0.34%)
occurrences causally related to treatment / all	0 / 12	0 / 11	1 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

<b>Non-serious adverse events</b>	Combination	Aliskiren	Enalapril
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1548 / 2347 (65.96%)	1446 / 2348 (61.58%)	1458 / 2345 (62.17%)
Vascular disorders			
Hypertension			
subjects affected / exposed	188 / 2347 (8.01%)	180 / 2348 (7.67%)	137 / 2345 (5.84%)
occurrences (all)	248	220	172
Hypotension			
subjects affected / exposed	409 / 2347 (17.43%)	308 / 2348 (13.12%)	332 / 2345 (14.16%)
occurrences (all)	618	403	439
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	199 / 2347 (8.48%)	238 / 2348 (10.14%)	184 / 2345 (7.85%)
occurrences (all)	235	292	220
Cardiac failure			
subjects affected / exposed	241 / 2347 (10.27%)	254 / 2348 (10.82%)	238 / 2345 (10.15%)
occurrences (all)	349	359	362
Nervous system disorders			
Dizziness			

subjects affected / exposed occurrences (all)	179 / 2347 (7.63%) 230	140 / 2348 (5.96%) 173	144 / 2345 (6.14%) 185
Blood and lymphatic system disorders Anaemia subjects affected / exposed occurrences (all)	124 / 2347 (5.28%) 141	115 / 2348 (4.90%) 120	111 / 2345 (4.73%) 118
General disorders and administration site conditions Oedema peripheral subjects affected / exposed occurrences (all)	182 / 2347 (7.75%) 233	183 / 2348 (7.79%) 241	176 / 2345 (7.51%) 216
Gastrointestinal disorders Diarrhoea subjects affected / exposed occurrences (all)	145 / 2347 (6.18%) 171	117 / 2348 (4.98%) 124	116 / 2345 (4.95%) 131
Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all)	285 / 2347 (12.14%) 372	223 / 2348 (9.50%) 281	286 / 2345 (12.20%) 354
Dyspnoea subjects affected / exposed occurrences (all)	204 / 2347 (8.69%) 268	216 / 2348 (9.20%) 318	213 / 2345 (9.08%) 274
Renal and urinary disorders Renal impairment subjects affected / exposed occurrences (all)	414 / 2347 (17.64%) 564	298 / 2348 (12.69%) 381	328 / 2345 (13.99%) 451
Infections and infestations Bronchitis subjects affected / exposed occurrences (all)	151 / 2347 (6.43%) 179	138 / 2348 (5.88%) 182	147 / 2345 (6.27%) 190
Nasopharyngitis subjects affected / exposed occurrences (all)	185 / 2347 (7.88%) 270	187 / 2348 (7.96%) 261	186 / 2345 (7.93%) 265
Metabolism and nutrition disorders Hyperkalaemia subjects affected / exposed occurrences (all)	469 / 2347 (19.98%) 717	283 / 2348 (12.05%) 387	350 / 2345 (14.93%) 481

Hypokalaemia			
subjects affected / exposed	130 / 2347 (5.54%)	149 / 2348 (6.35%)	116 / 2345 (4.95%)
occurrences (all)	178	223	157

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
20 January 2010	Amendment 1: The rationale of this amendment was to evaluate a non-invasive technique (BPro™ device) to measure central aortic pressure (CAP) in a representative subset of patients with chronic heart failure (NYHA Class II – IV) from the ATMOSPHERE population
29 October 2010	Amendment 2: This protocol amendment mainly served to add the contraindication for itraconazole and to allow the assessment of NT-proBNP at screening instead of BNP. Contraindication of itraconazole was added according to RMP (Risk Management Plan) requirement as it was observed that exposure to aliskiren was increased by the coadministration of cyclosporine and itraconazole. Therefore, concomitant use of aliskiren with potent inhibitors of p-glycoprotein (Pgp) (such as cyclosporine and itraconazole) is not recommended. Inclusion of patients with increased N-terminal pro-brain natriuretic peptide (NT-proBNP) was allowed in addition to patients with increased brain natriuretic peptide (BNP) as it appeared that some sites had only the possibility to measure NT-proBNP but not BNP.
30 March 2012	Amendment 3: The rationale of this local protocol amendment, which was only applicable for Costa Rica, followed a request from the local ethics committee to monitor fasting plasma glucose and HbA1c levels in all patients during the course of the trial.
30 April 2013	Amendment 4: This protocol amendment followed the request made by the CTFG on behalf of the HAs from the EU member states, after the submission of the ASTRONAUT study FIR to the HAs. Based on these results, the CTFG requested on 12-Feb-2013 that in the EU member states participating to the study, study drug be discontinued in all patients enrolled in ATMOSPHERE who have diabetes (but patients were to remain in the study and be followed up until trial end according to the study protocol), and no new patients with diabetes were allowed to be enrolled in the trial. Novartis complied with this request and amended the protocol to implement these changes consistently, across all participating countries worldwide. Other changes included in this amendment were to change from BNP to NT-proBNP in the analysis, which has the same clinical meaning but has a better chemical stability. Further, the statistical section was updated particularly in regard to the inclusion of an additional hypothesis (aliskiren/enalapril combination compared to enalapril monotherapy in nondiabetic patients), censoring rules for the time to event analysis and refinement in secondary objectives. One of the two secondary objectives (to evaluate whether aliskiren monotherapy and/or the combination of aliskiren/enalapril is superior to enalapril monotherapy in reducing the BNP level from baseline to predefined timepoint) was removed.

Notes:

### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported