

**Clinical trial results:**

**A multicenter, randomized, double-blind, parallel group, active-controlled study to evaluate the efficacy and safety of LCZ696 compared to enalapril on morbidity and mortality in patients with chronic heart failure and reduced ejection fraction**

**Summary**

EudraCT number	2009-015834-31
Trial protocol	PT IS GB ES DE HU NL SE IT RO SK FI FR DK BE CZ LT EE LV
Global end of trial date	27 May 2014

**Results information**

Result version number	v1 (current)
This version publication date	15 July 2016
First version publication date	15 July 2016

**Trial information****Trial identification**

Sponsor protocol code	CLCZ696B2314
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**Additional study identifiers**

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01035255
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	21 May 2014
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	21 May 2014
Was the trial ended prematurely?	Yes

Notes:

## General information about the trial

Main objective of the trial:

The primary objective of this study was to test if LCZ696 is superior to enalapril in delaying time to first occurrence of the composite endpoint, which was defined as either CV death or HF hospitalization, in patients with HF (NYHA class II – IV) and reduced left ventricular EF ( $\leq 40\%$ , changed to  $\leq 35\%$  by Protocol Amendment 1).

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	08 December 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	Argentina: 349
Country: Number of subjects enrolled	Belgium: 71
Country: Number of subjects enrolled	Brazil: 316
Country: Number of subjects enrolled	Bulgaria: 510
Country: Number of subjects enrolled	Canada: 168
Country: Number of subjects enrolled	Chile: 43
Country: Number of subjects enrolled	China: 353
Country: Number of subjects enrolled	Colombia: 164
Country: Number of subjects enrolled	Czech Republic: 212
Country: Number of subjects enrolled	Denmark: 106
Country: Number of subjects enrolled	Dominican Republic: 16
Country: Number of subjects enrolled	Ecuador: 103
Country: Number of subjects enrolled	Estonia: 29
Country: Number of subjects enrolled	Finland: 35
Country: Number of subjects enrolled	France: 69
Country: Number of subjects enrolled	Germany: 480
Country: Number of subjects enrolled	Guatemala: 138

Country: Number of subjects enrolled	Hong Kong: 23
Country: Number of subjects enrolled	Hungary: 444
Country: Number of subjects enrolled	Iceland: 18
Country: Number of subjects enrolled	India: 637
Country: Number of subjects enrolled	Israel: 112
Country: Number of subjects enrolled	Italy: 222
Country: Number of subjects enrolled	Korea, Democratic People's Republic of: 82
Country: Number of subjects enrolled	Latvia: 19
Country: Number of subjects enrolled	Lithuania: 22
Country: Number of subjects enrolled	Malaysia: 13
Country: Number of subjects enrolled	Mexico: 137
Country: Number of subjects enrolled	Netherlands: 169
Country: Number of subjects enrolled	Panama: 30
Country: Number of subjects enrolled	Peru: 142
Country: Number of subjects enrolled	Philippines: 223
Country: Number of subjects enrolled	Poland: 197
Country: Number of subjects enrolled	Portugal: 49
Country: Number of subjects enrolled	Romania: 135
Country: Number of subjects enrolled	Russian Federation: 856
Country: Number of subjects enrolled	Singapore: 32
Country: Number of subjects enrolled	Slovakia: 349
Country: Number of subjects enrolled	South Africa: 259
Country: Number of subjects enrolled	Spain: 196
Country: Number of subjects enrolled	Sweden: 29
Country: Number of subjects enrolled	Taiwan: 86
Country: Number of subjects enrolled	Thailand: 39
Country: Number of subjects enrolled	Turkey: 64
Country: Number of subjects enrolled	United Kingdom: 242
Country: Number of subjects enrolled	United States: 434
Country: Number of subjects enrolled	Venezuela, Bolivarian Republic of: 20
Worldwide total number of subjects	8442
EEA total number of subjects	3603

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)	4299
From 65 to 84 years	4143
85 years and over	0

## Subject disposition

### Recruitment

Recruitment details: -

### Pre-assignment

Screening details:

The FAS included all randomized patients with the following exclusions: 6 patients were excluded who did not qualify for randomization but were inadvertently randomized into the study and did not receive double-blind study medication; 37 patients were excluded because they were randomized at sites that were closed due to serious GCP violations

### Period 1

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

### Arms

Are arms mutually exclusive?	Yes
<b>Arm title</b>	LCZ696

Arm description:

Single-blind active run-in period consisted of treatment with enalapril 10 mg bid, followed by LCZ696 100 mg bid, and then LCZ696 200 mg bid over a total duration of 5 to 10 weeks. Temporary down-titration from LCZ696 200 mg bid to LCZ696 100 mg bid was allowed provided the patient was up-titrated back to LCZ696 200 mg bid and tolerated this dose for at least two weeks before being eligible for randomization. LCZ696 200 mg BID during double blind treatment period. Target doses: LCZ696 200 mg bid and enalapril 10 mg bid.

Arm type	Experimental
Investigational medicinal product name	sacubitril/valsartan
Investigational medicinal product code	LCZ696
Other name	sacubitril/valsartan
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

LCZ696 200 mg film-coated tablets orally bid

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

Single-blind active run-in period consisted of treatment with enalapril 10 mg bid, followed by LCZ696 100 mg bid, and then LCZ696 200 mg bid over a total duration of 5 to 10 weeks. Temporary down-titration from LCZ696 200 mg bid to LCZ696 100 mg bid was allowed provided the patient was up-titrated back to LCZ696 200 mg bid and tolerated this dose for at least two weeks before being eligible for randomization. Enalapril 10 mg BID during double blind treatment period. Target doses: LCZ696 200 mg bid and enalapril 10 mg bid.

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

Dosage and administration details:

Enalapril 10 mg film-coated tablet bid

<b>Number of subjects in period 1</b>	LCZ696	Enalapril
Started	4209	4233
Completed	3468	3371
Not completed	741	862
patient's request	15	13
Death	724	844
Lost to follow-up	2	5

## Baseline characteristics

### Reporting groups

Reporting group title	LCZ696
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Reporting group description:

Single-blind active run-in period consisted of treatment with enalapril 10 mg bid, followed by LCZ696 100 mg bid, and then LCZ696 200 mg bid over a total duration of 5 to 10 weeks. Temporary down-titration from LCZ696 200 mg bid to LCZ696 100 mg bid was allowed provided the patient was up-titrated back to LCZ696 200 mg bid and tolerated this dose for at least two weeks before being eligible for randomization. LCZ696 200 mg BID during double blind treatment period. Target doses: LCZ696 200 mg bid and enalapril 10 mg bid.

Reporting group title	Enalapril
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Reporting group description:

Single-blind active run-in period consisted of treatment with enalapril 10 mg bid, followed by LCZ696 100 mg bid, and then LCZ696 200 mg bid over a total duration of 5 to 10 weeks. Temporary down-titration from LCZ696 200 mg bid to LCZ696 100 mg bid was allowed provided the patient was up-titrated back to LCZ696 200 mg bid and tolerated this dose for at least two weeks before being eligible for randomization. Enalapril 10 mg BID during double blind treatment period. Target doses: LCZ696 200 mg bid and enalapril 10 mg bid.

Reporting group values	LCZ696	Enalapril	Total
Number of subjects	4209	4233	8442
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)	2122	2177	4299
From 65-84 years	2087	2056	4143
85 years and over	0	0	0
Age Continuous   Units: years			
arithmetic mean	63.78	63.82	-
standard deviation	± 11.52	± 11.25	-
Gender, Male/Female Units: participants			
Male	3321	3274	6595
Female	888	959	1847

## End points

### End points reporting groups

Reporting group title	LCZ696
Reporting group description: Single-blind active run-in period consisted of treatment with enalapril 10 mg bid, followed by LCZ696 100 mg bid, and then LCZ696 200 mg bid over a total duration of 5 to 10 weeks. Temporary down-titration from LCZ696 200 mg bid to LCZ696 100 mg bid was allowed provided the patient was up-titrated back to LCZ696 200 mg bid and tolerated this dose for at least two weeks before being eligible for randomization. LCZ696 200 mg BID during double blind treatment period. Target doses: LCZ696 200 mg bid and enalapril 10 mg bid.	
Reporting group title	Enalapril
Reporting group description: Single-blind active run-in period consisted of treatment with enalapril 10 mg bid, followed by LCZ696 100 mg bid, and then LCZ696 200 mg bid over a total duration of 5 to 10 weeks. Temporary down-titration from LCZ696 200 mg bid to LCZ696 100 mg bid was allowed provided the patient was up-titrated back to LCZ696 200 mg bid and tolerated this dose for at least two weeks before being eligible for randomization. Enalapril 10 mg BID during double blind treatment period. Target doses: LCZ696 200 mg bid and enalapril 10 mg bid.	

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

End point title	Number of participants that had first occurrence of the composite endpoint, which is defined as either CV death or HF hospitalization <sup>[1]</sup>
End point description: Number of participants that had first occurrence of the composite endpoint, which is defined as either CV death or HF hospitalization. The data is on the FAS population. Full Analysis Set (FAS) included all randomized patients but the following two exclusions: 6 patients who did not qualify for randomization but were inadvertently randomized into the study and did not receive double-blind study medication; 37 patients because they were randomized at sites that were closed due to serious GCP violations	
End point type	Primary
End point timeframe: up to 51 months	

#### Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No statistical analysis was planned for this primary outcome

End point values	LCZ696	Enalapril		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4187	4212		
Units: participants				
Primary Composite	914	1117		
CV death	558	693		
1st HF Hospitalization	537	658		

### Statistical analyses

No statistical analyses for this end point

## Secondary: Number of patients reported with all-cause mortality

End point title	Number of patients reported with all-cause mortality
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End point description:

This endpoint measures the number of participants that died from any cause. The data is on the FAS population up to March 31, 2014. Full Analysis Set (FAS) included all randomized patients but the following two exclusions: 6 patients who did not qualify for randomization but were inadvertently randomized into the study and did not receive double-blind study medication; 37 patients because they were randomized at sites that were closed due to serious GCP violations

End point type	Secondary
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End point timeframe:

up to 51 months

End point values	LCZ696	Enalapril		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4187	4212		
Units: participants	711	835		

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change from baseline to Month 8 for the Kansas City Cardiomyopathy Questionnaire (KCCQ) clinical summary score

End point title	Change from baseline to Month 8 for the Kansas City Cardiomyopathy Questionnaire (KCCQ) clinical summary score
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End point description:

Change from baseline to Month 8 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. The data is on the FAS population. Full Analysis Set (FAS) included all randomized patients but the following two exclusions: 6 patients who did not qualify for randomization but were inadvertently randomized into the study and did not receive double-blind study medication; 37 patients because they were randomized at sites that were closed due to serious GCP violations. The analysis included all FAS patients with at least one KCCQ data up-to Month 8.

End point type	Secondary
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End point timeframe:

Baseline, Month 8

End point values	LCZ696	Enalapril		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3643	3638		
Units: KCCQ Score				
least squares mean (standard error)	-2.99 (± 0.364)	-4.63 (± 0.364)		

## Statistical analyses

No statistical analyses for this end point

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### Secondary: Number of patients with first confirmed renal dysfunction

End point title	Number of patients with first confirmed renal dysfunction
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End point description:

Number of patients with first confirmed renal dysfunction. The data is on FAS population. Full Analysis Set (FAS) included all randomized patients but the following two exclusions: 6 patients who did not qualify for randomization but were inadvertently randomized into the study and did not receive double-blind study medication; 37 patients because they were randomized at sites that were closed due to serious GCP violations

End point type	Secondary
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End point timeframe:

up to 51 months

End point values	LCZ696	Enalapril		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4187	4212		
Units: participants	94	108		

## Statistical analyses

No statistical analyses for this end point

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### Secondary: Percentage of participants with New Onset of Atrial Fibrillation

End point title	Percentage of participants with New Onset of Atrial Fibrillation
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End point description:

Percentage of participants with New Onset of Atrial Fibrillation. The new onset atrial fibrillation (AF) analysis was based on a subset of FAS: i.e., for patients without a history of AF at baseline (patients with a history of AF were excluded from this analysis).

End point type	Secondary
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End point timeframe:

up to 51 months

<b>End point values</b>	LCZ696	Enalapril		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2670	2638		
Units: Percentage of participants				
number (not applicable)	3.15	3.15		

## Statistical analyses

No statistical analyses for this end point

### Secondary: Number of Patients Reported With Adjudicated Primary Causes of Death

End point title	Number of Patients Reported With Adjudicated Primary Causes of Death
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End point description:

Number of patients reported with adjudicated primary causes of death. The data is on Randomization population up to March 31, 2014. Randomized set (RAN): Consisted of all patients who received a randomization number, regardless of receiving trial medication.

End point type	Secondary
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End point timeframe:

Up to 51 month

<b>End point values</b>	LCZ696	Enalapril		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4209	4233		
Units: Participants				
Number of patients who died	714	837		
CV Death - Fatal MI	25	33		
CV Death - Pump Failure	147	185		
CV Death - Sudden Death	251	311		
CV Death - Presumed Sudden Death	26	23		
CV Death - Presumed CV Death	67	95		
CV Death - Fatal Stroke	30	34		
CV Death - Pulmonary Embolism	4	3		
CV Death - CV procedural	3	4		
Other CV Death	7	6		
Non-CV death - Infection	36	34		
Non-CV death - Malignancy	41	41		
Non-CV death - Renal	1	1		
Non-CV death - Accidental	13	6		
Non-CV death - Pulmonary	7	13		
Non-CV death - Suicide	4	1		
Non-CV death - GI	16	10		
Other Non-CV death	2	4		
Unknown Death	34	33		

## **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 are reported in this record from First Patient First Treatment until Last Patient Last Visit.

Adverse event reporting additional description:

Consistent with EudraCT disclosure specifications, Novartis has reported under the Serious adverse events field "number of deaths resulting from adverse events" all those deaths, resulting from serious adverse events that are deemed to be causally related to treatment by the investigator.

Assessment type	Systematic
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### Dictionary used

Dictionary name	MedDRA
Dictionary version	17.0

### Reporting groups

Reporting group title	Enalapril
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Reporting group description:

Single-blind active run-in period consisted of treatment with enalapril 10 mg bid, followed by LCZ696 100 mg bid, and then LCZ696 200 mg bid over a total duration of 5 to 10 weeks. Temporary down-titration from LCZ696 200 mg bid to LCZ696 100 mg bid was allowed provided the patient was up-titrated back to LCZ696 200 mg bid and tolerated this dose for at least two weeks before being eligible for randomization. Enalapril 10 mg BID during double blind treatment period

Reporting group title	LCZ696
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Reporting group description:

Single-blind active run-in period consisted of treatment with enalapril 10 mg bid, followed by LCZ696 100 mg bid, and then LCZ696 200 mg bid over a total duration of 5 to 10 weeks. Temporary down-titration from LCZ696 200 mg bid to LCZ696 100 mg bid was allowed provided the patient was up-titrated back to LCZ696 200 mg bid and tolerated this dose for at least two weeks before being eligible for randomization. LCZ696 200mg BID during double blind treatment period

<b>Serious adverse events</b>	Enalapril	LCZ696	
Total subjects affected by serious adverse events			
subjects affected / exposed	2142 / 4229 (50.65%)	1937 / 4203 (46.09%)	
number of deaths (all causes)	848	729	
number of deaths resulting from adverse events	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma gastric			
subjects affected / exposed	1 / 4229 (0.02%)	2 / 4203 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adenosquamous cell lung cancer			

subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Adenocarcinoma of colon		
subjects affected / exposed	8 / 4229 (0.19%)	3 / 4203 (0.07%)
occurrences causally related to treatment / all	0 / 8	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Basal cell carcinoma		
subjects affected / exposed	7 / 4229 (0.17%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 7	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
B-cell lymphoma		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Benign lung neoplasm		
subjects affected / exposed	2 / 4229 (0.05%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Benign neoplasm of adrenal gland		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Benign neoplasm		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Benign salivary gland neoplasm		
subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Benign neoplasm of bladder		

subjects affected / exposed	2 / 4229 (0.05%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder adenocarcinoma stage unspecified		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Biliary neoplasm		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder cancer		
subjects affected / exposed	5 / 4229 (0.12%)	11 / 4203 (0.26%)
occurrences causally related to treatment / all	0 / 7	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder cancer recurrent		
subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder transitional cell carcinoma		
subjects affected / exposed	1 / 4229 (0.02%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Bone cancer		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Brain neoplasm		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Brain neoplasm malignant		

subjects affected / exposed	2 / 4229 (0.05%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Breast cancer</b>		
subjects affected / exposed	3 / 4229 (0.07%)	6 / 4203 (0.14%)
occurrences causally related to treatment / all	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Breast cancer recurrent</b>		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Breast neoplasm</b>		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bronchial carcinoma</b>		
subjects affected / exposed	4 / 4229 (0.09%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 9	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bronchioloalveolar carcinoma</b>		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cerebral haemangioma</b>		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cervix carcinoma</b>		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cholangiocarcinoma</b>		

subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic lymphocytic leukaemia		
subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic myeloid leukaemia		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic myelomonocytic leukaemia		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Clear cell renal cell carcinoma		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Colon adenoma		
subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Colon cancer		
subjects affected / exposed	11 / 4229 (0.26%)	8 / 4203 (0.19%)
occurrences causally related to treatment / all	0 / 11	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Colon cancer metastatic		
subjects affected / exposed	0 / 4229 (0.00%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Colon neoplasm		

subjects affected / exposed	0 / 4229 (0.00%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Colorectal adenocarcinoma		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diffuse large B-cell lymphoma		
subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Colorectal cancer		
subjects affected / exposed	1 / 4229 (0.02%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric cancer		
subjects affected / exposed	3 / 4229 (0.07%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal cancer metastatic		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal carcinoma		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Glioblastoma		
subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Glioblastoma multiforme		

subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic cancer metastatic			
subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic cancer			
subjects affected / exposed	2 / 4229 (0.05%)	2 / 4203 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hodgkin's disease			
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypergammaglobulinaemia benign monoclonal			
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypopharyngeal neoplasm benign			
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inflammatory carcinoma of the breast			
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal adenocarcinoma			
subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Invasive ductal breast carcinoma			

subjects affected / exposed	2 / 4229 (0.05%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Laryngeal cancer		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Large intestine benign neoplasm		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Laryngeal cancer metastatic		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Laryngeal neoplasm		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lip and/or oral cavity cancer		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Leukaemia		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Liposarcoma		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lipoma		

subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Liposarcoma recurrent		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lung adenocarcinoma		
subjects affected / exposed	1 / 4229 (0.02%)	5 / 4203 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Lung cancer metastatic		
subjects affected / exposed	0 / 4229 (0.00%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Lung carcinoma cell type unspecified stage IV		
subjects affected / exposed	2 / 4229 (0.05%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lung neoplasm		
subjects affected / exposed	2 / 4229 (0.05%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lung neoplasm malignant		
subjects affected / exposed	13 / 4229 (0.31%)	11 / 4203 (0.26%)
occurrences causally related to treatment / all	0 / 14	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0
Malignant mediastinal neoplasm		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphoma		

subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Malignant melanoma		
subjects affected / exposed	1 / 4229 (0.02%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Malignant neoplasm of pleura		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Malignant neoplasm progression		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Meningioma		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Metastases to bone		
subjects affected / exposed	0 / 4229 (0.00%)	3 / 4203 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Meningioma benign		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Metastases to central nervous system		
subjects affected / exposed	1 / 4229 (0.02%)	3 / 4203 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Metastases to liver		

subjects affected / exposed	6 / 4229 (0.14%)	6 / 4203 (0.14%)
occurrences causally related to treatment / all	0 / 8	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Metastases to lung</b>		
subjects affected / exposed	1 / 4229 (0.02%)	4 / 4203 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Metastases to lymph nodes</b>		
subjects affected / exposed	2 / 4229 (0.05%)	3 / 4203 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Metastases to spine</b>		
subjects affected / exposed	2 / 4229 (0.05%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Metastases to spleen</b>		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Metastatic malignant melanoma</b>		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Metastatic neoplasm</b>		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Myelodysplastic syndrome</b>		
subjects affected / exposed	3 / 4229 (0.07%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Nasal neoplasm benign</b>		

subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Nasopharyngeal cancer</b>		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Neoplasm malignant</b>		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Neurilemmoma benign</b>		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Neuroma</b>		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Neuroendocrine tumour</b>		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Non-small cell lung cancer</b>		
subjects affected / exposed	0 / 4229 (0.00%)	3 / 4203 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Oesophageal adenocarcinoma</b>		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Oesophageal carcinoma</b>		

subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ovarian cancer		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatic neoplasm		
subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatic carcinoma		
subjects affected / exposed	2 / 4229 (0.05%)	4 / 4203 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Parathyroid tumour benign		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Prostate cancer		
subjects affected / exposed	14 / 4229 (0.33%)	8 / 4203 (0.19%)
occurrences causally related to treatment / all	0 / 14	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Plasma cell myeloma		
subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Prostate cancer metastatic		
subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Prostatic adenoma		

subjects affected / exposed	2 / 4229 (0.05%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal adenocarcinoma		
subjects affected / exposed	0 / 4229 (0.00%)	3 / 4203 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal cancer		
subjects affected / exposed	6 / 4229 (0.14%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 7	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rectosigmoid cancer		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Refractory cytopenia with unilineage dysplasia		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renal cancer		
subjects affected / exposed	4 / 4229 (0.09%)	3 / 4203 (0.07%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Renal cancer stage III		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal cell carcinoma		
subjects affected / exposed	2 / 4229 (0.05%)	3 / 4203 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Renal neoplasm		

subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Salivary gland adenoma		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Seborrhoeic keratosis		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Skin cancer		
subjects affected / exposed	2 / 4229 (0.05%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Small cell lung cancer		
subjects affected / exposed	2 / 4229 (0.05%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Soft tissue cancer		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Small intestine carcinoma		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Spermatocytic seminoma		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Squamous cell carcinoma		

subjects affected / exposed	3 / 4229 (0.07%)	3 / 4203 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Squamous cell carcinoma of lung		
subjects affected / exposed	0 / 4229 (0.00%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Squamous cell carcinoma of the tongue		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Thyroid cancer		
subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tonsil cancer		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Transitional cell carcinoma		
subjects affected / exposed	1 / 4229 (0.02%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Tumour ulceration		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Uterine cancer		
subjects affected / exposed	0 / 4229 (0.00%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Uterine leiomyoma		

subjects affected / exposed	2 / 4229 (0.05%)	0 / 4203 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Vascular disorders</b>			
<b>Accelerated hypertension</b>			
subjects affected / exposed	2 / 4229 (0.05%)	0 / 4203 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Aneurysm</b>			
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Angiodysplasia</b>			
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Aortic aneurysm</b>			
subjects affected / exposed	11 / 4229 (0.26%)	8 / 4203 (0.19%)	
occurrences causally related to treatment / all	0 / 11	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Aortic dilatation</b>			
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Aortic occlusion</b>			
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Aortic stenosis</b>			
subjects affected / exposed	2 / 4229 (0.05%)	6 / 4203 (0.14%)	
occurrences causally related to treatment / all	0 / 2	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Arterial occlusive disease</b>			

subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Arterial thrombosis		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Arteriosclerosis		
subjects affected / exposed	1 / 4229 (0.02%)	3 / 4203 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Arteriovenous fistula		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bleeding varicose vein		
subjects affected / exposed	2 / 4229 (0.05%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Blood pressure inadequately controlled		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Circulatory collapse		
subjects affected / exposed	8 / 4229 (0.19%)	5 / 4203 (0.12%)
occurrences causally related to treatment / all	0 / 8	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Deep vein thrombosis		
subjects affected / exposed	5 / 4229 (0.12%)	5 / 4203 (0.12%)
occurrences causally related to treatment / all	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic vascular disorder		

subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Extremity necrosis		
subjects affected / exposed	0 / 4229 (0.00%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Femoral artery embolism		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Femoral artery occlusion		
subjects affected / exposed	6 / 4229 (0.14%)	3 / 4203 (0.07%)
occurrences causally related to treatment / all	0 / 6	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Haematoma		
subjects affected / exposed	1 / 4229 (0.02%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhage		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertension		
subjects affected / exposed	12 / 4229 (0.28%)	13 / 4203 (0.31%)
occurrences causally related to treatment / all	0 / 15	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertensive crisis		
subjects affected / exposed	2 / 4229 (0.05%)	7 / 4203 (0.17%)
occurrences causally related to treatment / all	0 / 2	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertensive emergency		

subjects affected / exposed	2 / 4229 (0.05%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoperfusion		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypotension		
subjects affected / exposed	68 / 4229 (1.61%)	59 / 4203 (1.40%)
occurrences causally related to treatment / all	34 / 73	23 / 61
deaths causally related to treatment / all	0 / 0	0 / 0
Iliac artery occlusion		
subjects affected / exposed	3 / 4229 (0.07%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypovolaemic shock		
subjects affected / exposed	2 / 4229 (0.05%)	5 / 4203 (0.12%)
occurrences causally related to treatment / all	0 / 2	1 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Ischaemia		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intermittent claudication		
subjects affected / exposed	3 / 4229 (0.07%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Jugular vein thrombosis		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphatic fistula		

subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphocele		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphoedema		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Orthostatic hypotension		
subjects affected / exposed	3 / 4229 (0.07%)	5 / 4203 (0.12%)
occurrences causally related to treatment / all	1 / 3	5 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral arterial occlusive disease		
subjects affected / exposed	13 / 4229 (0.31%)	22 / 4203 (0.52%)
occurrences causally related to treatment / all	0 / 13	0 / 28
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery aneurysm		
subjects affected / exposed	1 / 4229 (0.02%)	3 / 4203 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery stenosis		
subjects affected / exposed	2 / 4229 (0.05%)	4 / 4203 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral circulatory failure		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery thrombosis		

subjects affected / exposed	3 / 4229 (0.07%)	4 / 4203 (0.10%)
occurrences causally related to treatment / all	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral ischaemia		
subjects affected / exposed	8 / 4229 (0.19%)	18 / 4203 (0.43%)
occurrences causally related to treatment / all	0 / 9	0 / 22
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral embolism		
subjects affected / exposed	2 / 4229 (0.05%)	4 / 4203 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral vascular disorder		
subjects affected / exposed	5 / 4229 (0.12%)	7 / 4203 (0.17%)
occurrences causally related to treatment / all	0 / 7	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Phlebitis		
subjects affected / exposed	0 / 4229 (0.00%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Polyarteritis nodosa		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Shock		
subjects affected / exposed	5 / 4229 (0.12%)	4 / 4203 (0.10%)
occurrences causally related to treatment / all	0 / 5	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Shock haemorrhagic		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Subgaleal haematoma		

subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Superior vena cava syndrome		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Thrombophlebitis		
subjects affected / exposed	3 / 4229 (0.07%)	3 / 4203 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Thrombophlebitis superficial		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Thrombosis		
subjects affected / exposed	2 / 4229 (0.05%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	1 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Varicose vein		
subjects affected / exposed	2 / 4229 (0.05%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular compression		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vasculitis		
subjects affected / exposed	0 / 4229 (0.00%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Venous haemorrhage		

subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vein collapse			
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Venous thrombosis			
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Venous insufficiency			
subjects affected / exposed	3 / 4229 (0.07%)	0 / 4203 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Venous thrombosis limb			
subjects affected / exposed	2 / 4229 (0.05%)	1 / 4203 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
Cardiac pacemaker insertion			
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endotracheal intubation			
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Implantable defibrillator insertion			
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphadenectomy			

subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Resuscitation			
subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroidectomy			
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pregnancy, puerperium and perinatal conditions			
Pregnancy			
subjects affected / exposed	0 / 4229 (0.00%)	2 / 4203 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Accidental death			
subjects affected / exposed	0 / 4229 (0.00%)	2 / 4203 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asthenia			
subjects affected / exposed	9 / 4229 (0.21%)	9 / 4203 (0.21%)	
occurrences causally related to treatment / all	2 / 9	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac death			
subjects affected / exposed	114 / 4229 (2.70%)	85 / 4203 (2.02%)	
occurrences causally related to treatment / all	1 / 115	1 / 85	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac complication associated with device			

subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Chest discomfort		
subjects affected / exposed	1 / 4229 (0.02%)	3 / 4203 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Chest pain		
subjects affected / exposed	3 / 4229 (0.07%)	3 / 4203 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Chills		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Concomitant disease aggravated		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Death		
subjects affected / exposed	78 / 4229 (1.84%)	56 / 4203 (1.33%)
occurrences causally related to treatment / all	2 / 78	2 / 56
deaths causally related to treatment / all	0 / 0	0 / 0
Device battery issue		
subjects affected / exposed	8 / 4229 (0.19%)	11 / 4203 (0.26%)
occurrences causally related to treatment / all	0 / 8	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Device dislocation		
subjects affected / exposed	3 / 4229 (0.07%)	3 / 4203 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Device breakage		

subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Device failure		
subjects affected / exposed	5 / 4229 (0.12%)	6 / 4203 (0.14%)
occurrences causally related to treatment / all	0 / 5	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Device issue		
subjects affected / exposed	2 / 4229 (0.05%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Device leakage		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Device lead damage		
subjects affected / exposed	1 / 4229 (0.02%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Device malfunction		
subjects affected / exposed	11 / 4229 (0.26%)	15 / 4203 (0.36%)
occurrences causally related to treatment / all	0 / 11	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0
Device occlusion		
subjects affected / exposed	2 / 4229 (0.05%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Device stimulation issue		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Disease progression		

subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Drowning		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Exercise tolerance decreased		
subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Euthanasia		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Fatigue		
subjects affected / exposed	10 / 4229 (0.24%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 12	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gait disturbance		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
General physical health deterioration		
subjects affected / exposed	3 / 4229 (0.07%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Generalised oedema		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hernia		

subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hernia obstructive		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Impaired healing		
subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperthermia		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Implant site haematoma		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Implant site inflammation		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Implant site reaction		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Implant site ulcer		
subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Inflammation		

subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Local swelling		
subjects affected / exposed	3 / 4229 (0.07%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Malaise		
subjects affected / exposed	2 / 4229 (0.05%)	4 / 4203 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Medical device complication		
subjects affected / exposed	1 / 4229 (0.02%)	5 / 4203 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Medical device pain		
subjects affected / exposed	3 / 4229 (0.07%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Medical device site reaction		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Multi-organ disorder		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Multi-organ failure		
subjects affected / exposed	15 / 4229 (0.35%)	14 / 4203 (0.33%)
occurrences causally related to treatment / all	0 / 15	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0
Necrosis		

subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Non-cardiac chest pain		
subjects affected / exposed	36 / 4229 (0.85%)	33 / 4203 (0.79%)
occurrences causally related to treatment / all	0 / 51	0 / 39
deaths causally related to treatment / all	0 / 0	0 / 0
Oedema		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oedema due to cardiac disease		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oedema peripheral		
subjects affected / exposed	15 / 4229 (0.35%)	10 / 4203 (0.24%)
occurrences causally related to treatment / all	0 / 22	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0
Pacemaker generated arrhythmia		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Perforated ulcer		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Sudden cardiac death		
subjects affected / exposed	69 / 4229 (1.63%)	67 / 4203 (1.59%)
occurrences causally related to treatment / all	3 / 69	2 / 67
deaths causally related to treatment / all	0 / 0	0 / 0
Pyrexia		

subjects affected / exposed	12 / 4229 (0.28%)	9 / 4203 (0.21%)	
occurrences causally related to treatment / all	0 / 12	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Sudden death</b>			
subjects affected / exposed	78 / 4229 (1.84%)	66 / 4203 (1.57%)	
occurrences causally related to treatment / all	1 / 79	2 / 66	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Temperature regulation disorder</b>			
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Vessel puncture site haemorrhage</b>			
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Vessel puncture site haematoma</b>			
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Immune system disorders</b>			
<b>Allergy to arthropod sting</b>			
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Anaphylactic reaction</b>			
subjects affected / exposed	0 / 4229 (0.00%)	2 / 4203 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Anaphylactic shock</b>			
subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Drug hypersensitivity</b>			

subjects affected / exposed	5 / 4229 (0.12%)	1 / 4203 (0.02%)	
occurrences causally related to treatment / all	1 / 5	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Sarcoidosis</b>			
subjects affected / exposed	0 / 4229 (0.00%)	2 / 4203 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Hypersensitivity</b>			
subjects affected / exposed	0 / 4229 (0.00%)	2 / 4203 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Reproductive system and breast disorders</b>			
<b>Benign prostatic hyperplasia</b>			
subjects affected / exposed	9 / 4229 (0.21%)	8 / 4203 (0.19%)	
occurrences causally related to treatment / all	0 / 10	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Acquired phimosis</b>			
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Endometrial hyperplasia</b>			
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Breast pain</b>			
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Cervical polyp</b>			
subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Menorrhagia</b>			

subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Erectile dysfunction		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ovarian cyst		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Perineal pain		
subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Postmenopausal haemorrhage		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Prostatic obstruction		
subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Prostatitis		
subjects affected / exposed	3 / 4229 (0.07%)	3 / 4203 (0.07%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Uterine haemorrhage		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vaginal haemorrhage		

subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine polyp			
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vaginal relaxation			
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Acute pulmonary oedema			
subjects affected / exposed	19 / 4229 (0.45%)	20 / 4203 (0.48%)	
occurrences causally related to treatment / all	0 / 22	0 / 23	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute respiratory distress syndrome			
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute respiratory failure			
subjects affected / exposed	11 / 4229 (0.26%)	11 / 4203 (0.26%)	
occurrences causally related to treatment / all	0 / 12	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asphyxia			
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atelectasis			
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asthma			

subjects affected / exposed	6 / 4229 (0.14%)	4 / 4203 (0.10%)
occurrences causally related to treatment / all	0 / 11	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bronchiectasis</b>		
subjects affected / exposed	1 / 4229 (0.02%)	3 / 4203 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bronchospasm</b>		
subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bronchitis chronic</b>		
subjects affected / exposed	6 / 4229 (0.14%)	3 / 4203 (0.07%)
occurrences causally related to treatment / all	0 / 6	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Chronic respiratory failure</b>		
subjects affected / exposed	0 / 4229 (0.00%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Chronic obstructive pulmonary disease</b>		
subjects affected / exposed	46 / 4229 (1.09%)	40 / 4203 (0.95%)
occurrences causally related to treatment / all	0 / 61	0 / 63
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cough</b>		
subjects affected / exposed	9 / 4229 (0.21%)	3 / 4203 (0.07%)
occurrences causally related to treatment / all	6 / 10	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Dysphonia</b>		
subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Dyspnoea</b>		

subjects affected / exposed	57 / 4229 (1.35%)	51 / 4203 (1.21%)
occurrences causally related to treatment / all	1 / 71	4 / 58
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Dyspnoea exertional</b>		
subjects affected / exposed	4 / 4229 (0.09%)	5 / 4203 (0.12%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Dyspnoea paroxysmal nocturnal</b>		
subjects affected / exposed	2 / 4229 (0.05%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Emphysema</b>		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Haemoptysis</b>		
subjects affected / exposed	11 / 4229 (0.26%)	4 / 4203 (0.10%)
occurrences causally related to treatment / all	0 / 11	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Epistaxis</b>		
subjects affected / exposed	7 / 4229 (0.17%)	7 / 4203 (0.17%)
occurrences causally related to treatment / all	0 / 7	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hiccups</b>		
subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Haemothorax</b>		
subjects affected / exposed	0 / 4229 (0.00%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hydrothorax</b>		

subjects affected / exposed	2 / 4229 (0.05%)	3 / 4203 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hypoxia</b>		
subjects affected / exposed	7 / 4229 (0.17%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 7	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Interstitial lung disease</b>		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Laryngeal oedema</b>		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Lung infiltration</b>		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Laryngospasm</b>		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Nasal polyps</b>		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Nocturnal dyspnoea</b>		
subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Obstructive airways disorder</b>		

subjects affected / exposed	0 / 4229 (0.00%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Orthopnoea</b>		
subjects affected / exposed	3 / 4229 (0.07%)	4 / 4203 (0.10%)
occurrences causally related to treatment / all	0 / 6	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pleural effusion</b>		
subjects affected / exposed	19 / 4229 (0.45%)	16 / 4203 (0.38%)
occurrences causally related to treatment / all	0 / 21	0 / 18
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pleurisy</b>		
subjects affected / exposed	1 / 4229 (0.02%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pneumonia aspiration</b>		
subjects affected / exposed	8 / 4229 (0.19%)	5 / 4203 (0.12%)
occurrences causally related to treatment / all	0 / 8	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pneumothorax</b>		
subjects affected / exposed	3 / 4229 (0.07%)	6 / 4203 (0.14%)
occurrences causally related to treatment / all	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pneumonitis</b>		
subjects affected / exposed	3 / 4229 (0.07%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pneumothorax spontaneous</b>		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pulmonary congestion</b>		

subjects affected / exposed	6 / 4229 (0.14%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 6	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Productive cough</b>		
subjects affected / exposed	2 / 4229 (0.05%)	3 / 4203 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pulmonary fibrosis</b>		
subjects affected / exposed	2 / 4229 (0.05%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pulmonary embolism</b>		
subjects affected / exposed	23 / 4229 (0.54%)	22 / 4203 (0.52%)
occurrences causally related to treatment / all	1 / 24	0 / 22
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pulmonary infarction</b>		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pulmonary haemorrhage</b>		
subjects affected / exposed	2 / 4229 (0.05%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pulmonary hypertension</b>		
subjects affected / exposed	5 / 4229 (0.12%)	3 / 4203 (0.07%)
occurrences causally related to treatment / all	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pulmonary microemboli</b>		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pulmonary mass</b>		

subjects affected / exposed	2 / 4229 (0.05%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Rales</b>		
subjects affected / exposed	4 / 4229 (0.09%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pulmonary oedema</b>		
subjects affected / exposed	21 / 4229 (0.50%)	21 / 4203 (0.50%)
occurrences causally related to treatment / all	0 / 23	0 / 26
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Respiratory arrest</b>		
subjects affected / exposed	2 / 4229 (0.05%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Respiratory distress</b>		
subjects affected / exposed	1 / 4229 (0.02%)	5 / 4203 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Respiratory acidosis</b>		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Respiratory failure</b>		
subjects affected / exposed	26 / 4229 (0.61%)	25 / 4203 (0.59%)
occurrences causally related to treatment / all	1 / 26	0 / 25
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Respiratory fatigue</b>		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Tachypnoea</b>		

subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sleep apnoea syndrome			
subjects affected / exposed	2 / 4229 (0.05%)	3 / 4203 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vocal cord leukoplakia			
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tracheal stenosis			
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Alcohol abuse			
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol withdrawal syndrome			
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anxiety			
subjects affected / exposed	2 / 4229 (0.05%)	3 / 4203 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcoholism			
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Completed suicide			

subjects affected / exposed	1 / 4229 (0.02%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Confusional state		
subjects affected / exposed	8 / 4229 (0.19%)	6 / 4203 (0.14%)
occurrences causally related to treatment / all	0 / 8	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Delirium		
subjects affected / exposed	4 / 4229 (0.09%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Delirium tremens		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Depression		
subjects affected / exposed	0 / 4229 (0.00%)	5 / 4203 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Disorientation		
subjects affected / exposed	2 / 4229 (0.05%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Emotional distress		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Generalised anxiety disorder		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hypochondriasis		

subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hallucination		
subjects affected / exposed	2 / 4229 (0.05%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Insomnia		
subjects affected / exposed	2 / 4229 (0.05%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Major depression		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Mental status changes		
subjects affected / exposed	0 / 4229 (0.00%)	4 / 4203 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Mental disorder		
subjects affected / exposed	1 / 4229 (0.02%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Mental disorder due to a general medical condition		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Panic disorder		
subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Mood disorder due to a general medical condition		

subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Psychotic disorder</b>		
subjects affected / exposed	2 / 4229 (0.05%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Psychiatric symptom</b>		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Psychotic disorder due to a general medical condition</b>		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Schizophrenia</b>		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Somatisation disorder</b>		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Somatoform disorder cardiovascular</b>		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Somatoform disorder gastrointestinal</b>		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Suicide attempt</b>		

subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Hepatobiliary disorders</b>			
Acute hepatic failure			
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile duct stone			
subjects affected / exposed	3 / 4229 (0.07%)	4 / 4203 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary colic			
subjects affected / exposed	2 / 4229 (0.05%)	0 / 4203 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary dilatation			
subjects affected / exposed	0 / 4229 (0.00%)	2 / 4203 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac cirrhosis			
subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangitis acute			
subjects affected / exposed	0 / 4229 (0.00%)	4 / 4203 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangitis			
subjects affected / exposed	1 / 4229 (0.02%)	2 / 4203 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis			

subjects affected / exposed	8 / 4229 (0.19%)	5 / 4203 (0.12%)
occurrences causally related to treatment / all	0 / 8	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Cholecystitis acute		
subjects affected / exposed	12 / 4229 (0.28%)	12 / 4203 (0.29%)
occurrences causally related to treatment / all	0 / 12	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0
Cholecystitis chronic		
subjects affected / exposed	1 / 4229 (0.02%)	3 / 4203 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Cholelithiasis		
subjects affected / exposed	17 / 4229 (0.40%)	10 / 4203 (0.24%)
occurrences causally related to treatment / all	0 / 17	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Cholestasis		
subjects affected / exposed	2 / 4229 (0.05%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gallbladder perforation		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic congestion		
subjects affected / exposed	3 / 4229 (0.07%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic cirrhosis		
subjects affected / exposed	5 / 4229 (0.12%)	3 / 4203 (0.07%)
occurrences causally related to treatment / all	0 / 6	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic failure		

subjects affected / exposed	4 / 4229 (0.09%)	5 / 4203 (0.12%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic function abnormal		
subjects affected / exposed	2 / 4229 (0.05%)	3 / 4203 (0.07%)
occurrences causally related to treatment / all	1 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic ischaemia		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic steatosis		
subjects affected / exposed	1 / 4229 (0.02%)	3 / 4203 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatitis		
subjects affected / exposed	1 / 4229 (0.02%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatitis acute		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatitis toxic		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatocellular injury		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatomegaly		

subjects affected / exposed	2 / 4229 (0.05%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatorenal syndrome		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hydrocholecystis		
subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatotoxicity		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperbilirubinaemia		
subjects affected / exposed	2 / 4229 (0.05%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ischaemic hepatitis		
subjects affected / exposed	2 / 4229 (0.05%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Jaundice		
subjects affected / exposed	0 / 4229 (0.00%)	5 / 4203 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Jaundice cholestatic		
subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Liver disorder		

subjects affected / exposed	2 / 4229 (0.05%)	0 / 4203 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver injury			
subjects affected / exposed	2 / 4229 (0.05%)	1 / 4203 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Portal hypertension			
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Portal vein thrombosis			
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Acid base balance abnormal			
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alanine aminotransferase increased			
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood creatinine increased			
subjects affected / exposed	2 / 4229 (0.05%)	4 / 4203 (0.10%)	
occurrences causally related to treatment / all	1 / 2	1 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood albumin decreased			

subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Blood potassium decreased		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Blood glucose increased		
subjects affected / exposed	0 / 4229 (0.00%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Blood pressure systolic decreased		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Blood pressure decreased		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac function test abnormal		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Blood sodium decreased		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
C-reactive protein increased		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Coagulation factor increased		

subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Coagulation time prolonged		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Creatinine renal clearance decreased		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ejection fraction		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ejection fraction decreased		
subjects affected / exposed	2 / 4229 (0.05%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Electrocardiogram QRS complex abnormal		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Escherichia test positive		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Glomerular filtration rate decreased		
subjects affected / exposed	1 / 4229 (0.02%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 1	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric pH decreased		

subjects affected / exposed	2 / 4229 (0.05%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Heart rate decreased		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic enzyme increased		
subjects affected / exposed	0 / 4229 (0.00%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Haemoglobin decreased		
subjects affected / exposed	2 / 4229 (0.05%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
International normalised ratio abnormal		
subjects affected / exposed	2 / 4229 (0.05%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
International normalised ratio increased		
subjects affected / exposed	8 / 4229 (0.19%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	1 / 9	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oxygen saturation decreased		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Liver function test abnormal		
subjects affected / exposed	3 / 4229 (0.07%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	2 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Prothrombin time prolonged		

subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Respiratory rate increased</b>			
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Prothrombin time abnormal</b>			
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Troponin increased</b>			
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Urine output decreased</b>			
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Weight decreased</b>			
subjects affected / exposed	5 / 4229 (0.12%)	5 / 4203 (0.12%)	
occurrences causally related to treatment / all	0 / 5	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Venous pressure jugular increased</b>			
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Weight increased</b>			
subjects affected / exposed	2 / 4229 (0.05%)	1 / 4203 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Injury, poisoning and procedural complications</b>			
Abdominal injury			

subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Accident</b>			
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Alcohol poisoning</b>			
subjects affected / exposed	2 / 4229 (0.05%)	1 / 4203 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Animal bite</b>			
subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Ankle fracture</b>			
subjects affected / exposed	2 / 4229 (0.05%)	0 / 4203 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Arterial restenosis</b>			
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Bone contusion</b>			
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Brain contusion</b>			
subjects affected / exposed	2 / 4229 (0.05%)	1 / 4203 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Cardiac function disturbance postoperative</b>			

subjects affected / exposed	3 / 4229 (0.07%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac contusion		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac valve replacement complication		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac valve rupture		
subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Chemical peritonitis		
subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Chest injury		
subjects affected / exposed	1 / 4229 (0.02%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Clavicle fracture		
subjects affected / exposed	1 / 4229 (0.02%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Concussion		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Compression fracture		

subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Contusion		
subjects affected / exposed	4 / 4229 (0.09%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	1 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery restenosis		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Craniocerebral injury		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cystitis radiation		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Excoriation		
subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Extradural haematoma		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Face injury		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Eyeball rupture		

subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Facial bones fracture		
subjects affected / exposed	1 / 4229 (0.02%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Fall		
subjects affected / exposed	10 / 4229 (0.24%)	6 / 4203 (0.14%)
occurrences causally related to treatment / all	1 / 10	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Femoral neck fracture		
subjects affected / exposed	7 / 4229 (0.17%)	5 / 4203 (0.12%)
occurrences causally related to treatment / all	0 / 9	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Femur fracture		
subjects affected / exposed	7 / 4229 (0.17%)	6 / 4203 (0.14%)
occurrences causally related to treatment / all	0 / 7	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Fibula fracture		
subjects affected / exposed	2 / 4229 (0.05%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Foot fracture		
subjects affected / exposed	2 / 4229 (0.05%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Forearm fracture		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Foreign body		

subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Graft complication		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hand fracture		
subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Head injury		
subjects affected / exposed	5 / 4229 (0.12%)	6 / 4203 (0.14%)
occurrences causally related to treatment / all	0 / 5	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Hip fracture		
subjects affected / exposed	12 / 4229 (0.28%)	6 / 4203 (0.14%)
occurrences causally related to treatment / all	0 / 12	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Humerus fracture		
subjects affected / exposed	3 / 4229 (0.07%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Incisional hernia		
subjects affected / exposed	1 / 4229 (0.02%)	3 / 4203 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Jaw fracture		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Joint dislocation		

subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Joint injury		
subjects affected / exposed	0 / 4229 (0.00%)	4 / 4203 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Laceration		
subjects affected / exposed	1 / 4229 (0.02%)	5 / 4203 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Limb traumatic amputation		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lower limb fracture		
subjects affected / exposed	2 / 4229 (0.05%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Lumbar vertebral fracture		
subjects affected / exposed	1 / 4229 (0.02%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Median nerve injury		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Medication error		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Meniscus injury		

subjects affected / exposed	2 / 4229 (0.05%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Multiple fractures		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Multiple injuries		
subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Muscle rupture		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Overdose		
subjects affected / exposed	5 / 4229 (0.12%)	3 / 4203 (0.07%)
occurrences causally related to treatment / all	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Patella fracture		
subjects affected / exposed	3 / 4229 (0.07%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pelvic fracture		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post concussion syndrome		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural complication		

subjects affected / exposed	2 / 4229 (0.05%)	2 / 4203 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural discharge			
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural fistula			
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural haematoma			
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural haemorrhage			
subjects affected / exposed	2 / 4229 (0.05%)	1 / 4203 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural myocardial infarction			
subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative renal failure			
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative thoracic procedure complication			
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative wound complication			

subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Procedural complication		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Procedural haemorrhage		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pubis fracture		
subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Radiation proctitis		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Road traffic accident		
subjects affected / exposed	3 / 4229 (0.07%)	7 / 4203 (0.17%)
occurrences causally related to treatment / all	0 / 3	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Sacroiliac fracture		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rib fracture		
subjects affected / exposed	1 / 4229 (0.02%)	4 / 4203 (0.10%)
occurrences causally related to treatment / all	0 / 1	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Seroma		

subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Scapula fracture		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Skull fracture		
subjects affected / exposed	2 / 4229 (0.05%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Soft tissue injury		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal cord injury lumbar		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal fracture		
subjects affected / exposed	3 / 4229 (0.07%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal compression fracture		
subjects affected / exposed	4 / 4229 (0.09%)	3 / 4203 (0.07%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Subdural haematoma		
subjects affected / exposed	5 / 4229 (0.12%)	11 / 4203 (0.26%)
occurrences causally related to treatment / all	0 / 5	1 / 12
deaths causally related to treatment / all	0 / 0	0 / 0
Subcutaneous haematoma		

subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Thermal burn		
subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Subdural haemorrhage		
subjects affected / exposed	2 / 4229 (0.05%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tendon rupture		
subjects affected / exposed	0 / 4229 (0.00%)	3 / 4203 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Thoracic vertebral fracture		
subjects affected / exposed	3 / 4229 (0.07%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tibia fracture		
subjects affected / exposed	2 / 4229 (0.05%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Toxicity to various agents		
subjects affected / exposed	9 / 4229 (0.21%)	8 / 4203 (0.19%)
occurrences causally related to treatment / all	0 / 14	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Traumatic haematoma		
subjects affected / exposed	2 / 4229 (0.05%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ulna fracture		

subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Vascular graft complication</b>		
subjects affected / exposed	0 / 4229 (0.00%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Upper limb fracture</b>		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Vascular graft occlusion</b>		
subjects affected / exposed	0 / 4229 (0.00%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Vascular graft thrombosis</b>		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Vascular pseudoaneurysm</b>		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Vascular procedure complication</b>		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Wound</b>		
subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Wound necrosis</b>		

subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound dehiscence			
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital, familial and genetic disorders			
Cryptorchism			
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Exomphalos			
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal arteriovenous malformation			
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Homocystinaemia			
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydrocele			
subjects affected / exposed	0 / 4229 (0.00%)	2 / 4203 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertrophic cardiomyopathy			
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sickle cell anaemia with crisis			

subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Cardiac disorders</b>			
Acute coronary syndrome			
subjects affected / exposed	18 / 4229 (0.43%)	18 / 4203 (0.43%)	
occurrences causally related to treatment / all	0 / 18	0 / 18	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute myocardial infarction			
subjects affected / exposed	68 / 4229 (1.61%)	69 / 4203 (1.64%)	
occurrences causally related to treatment / all	2 / 73	0 / 74	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute left ventricular failure			
subjects affected / exposed	5 / 4229 (0.12%)	4 / 4203 (0.10%)	
occurrences causally related to treatment / all	1 / 6	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angina pectoris			
subjects affected / exposed	62 / 4229 (1.47%)	55 / 4203 (1.31%)	
occurrences causally related to treatment / all	0 / 69	1 / 61	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adams-Stokes syndrome			
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angina unstable			
subjects affected / exposed	51 / 4229 (1.21%)	53 / 4203 (1.26%)	
occurrences causally related to treatment / all	1 / 60	0 / 62	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve incompetence			
subjects affected / exposed	4 / 4229 (0.09%)	3 / 4203 (0.07%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve stenosis			

subjects affected / exposed	4 / 4229 (0.09%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Arrhythmia</b>		
subjects affected / exposed	21 / 4229 (0.50%)	23 / 4203 (0.55%)
occurrences causally related to treatment / all	3 / 21	0 / 23
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Arrhythmia supraventricular</b>		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Arteriosclerosis coronary artery</b>		
subjects affected / exposed	4 / 4229 (0.09%)	4 / 4203 (0.10%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Atrial fibrillation</b>		
subjects affected / exposed	113 / 4229 (2.67%)	108 / 4203 (2.57%)
occurrences causally related to treatment / all	1 / 128	5 / 127
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Arteriospasm coronary</b>		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Atrial flutter</b>		
subjects affected / exposed	18 / 4229 (0.43%)	11 / 4203 (0.26%)
occurrences causally related to treatment / all	0 / 19	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Atrial tachycardia</b>		
subjects affected / exposed	1 / 4229 (0.02%)	7 / 4203 (0.17%)
occurrences causally related to treatment / all	0 / 1	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Atrioventricular block</b>		

subjects affected / exposed	5 / 4229 (0.12%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Atrioventricular block complete</b>		
subjects affected / exposed	10 / 4229 (0.24%)	13 / 4203 (0.31%)
occurrences causally related to treatment / all	0 / 10	1 / 13
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Atrioventricular block first degree</b>		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Atrioventricular block second degree</b>		
subjects affected / exposed	5 / 4229 (0.12%)	6 / 4203 (0.14%)
occurrences causally related to treatment / all	0 / 5	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Atrioventricular dissociation</b>		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bradycardia</b>		
subjects affected / exposed	13 / 4229 (0.31%)	11 / 4203 (0.26%)
occurrences causally related to treatment / all	1 / 13	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bradyarrhythmia</b>		
subjects affected / exposed	4 / 4229 (0.09%)	3 / 4203 (0.07%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cardiac aneurysm</b>		
subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bundle branch block left</b>		

subjects affected / exposed	3 / 4229 (0.07%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Bundle branch block right		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac arrest		
subjects affected / exposed	56 / 4229 (1.32%)	30 / 4203 (0.71%)
occurrences causally related to treatment / all	2 / 58	2 / 30
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac asthma		
subjects affected / exposed	3 / 4229 (0.07%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac disorder		
subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac discomfort		
subjects affected / exposed	3 / 4229 (0.07%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac failure chronic		
subjects affected / exposed	135 / 4229 (3.19%)	112 / 4203 (2.66%)
occurrences causally related to treatment / all	11 / 191	4 / 152
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac failure		
subjects affected / exposed	649 / 4229 (15.35%)	588 / 4203 (13.99%)
occurrences causally related to treatment / all	30 / 1042	20 / 876
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac failure acute		

subjects affected / exposed	93 / 4229 (2.20%)	67 / 4203 (1.59%)
occurrences causally related to treatment / all	1 / 131	3 / 81
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac fibrillation		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac failure congestive		
subjects affected / exposed	140 / 4229 (3.31%)	112 / 4203 (2.66%)
occurrences causally related to treatment / all	10 / 221	3 / 184
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac hypertrophy		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac perforation		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac tamponade		
subjects affected / exposed	2 / 4229 (0.05%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac valve disease		
subjects affected / exposed	2 / 4229 (0.05%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac ventricular thrombosis		
subjects affected / exposed	3 / 4229 (0.07%)	3 / 4203 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Cardio-respiratory arrest		

subjects affected / exposed	27 / 4229 (0.64%)	25 / 4203 (0.59%)
occurrences causally related to treatment / all	0 / 27	0 / 25
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cardiogenic shock</b>		
subjects affected / exposed	38 / 4229 (0.90%)	19 / 4203 (0.45%)
occurrences causally related to treatment / all	1 / 39	1 / 19
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cardiopulmonary failure</b>		
subjects affected / exposed	13 / 4229 (0.31%)	7 / 4203 (0.17%)
occurrences causally related to treatment / all	0 / 13	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cardiomyopathy</b>		
subjects affected / exposed	10 / 4229 (0.24%)	6 / 4203 (0.14%)
occurrences causally related to treatment / all	0 / 12	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cardiomegaly</b>		
subjects affected / exposed	5 / 4229 (0.12%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cardiorenal syndrome</b>		
subjects affected / exposed	2 / 4229 (0.05%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	1 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cardiovascular disorder</b>		
subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cardiovascular insufficiency</b>		
subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Chordae tendinae rupture</b>		

subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Congestive cardiomyopathy		
subjects affected / exposed	29 / 4229 (0.69%)	13 / 4203 (0.31%)
occurrences causally related to treatment / all	0 / 30	0 / 17
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery disease		
subjects affected / exposed	38 / 4229 (0.90%)	35 / 4203 (0.83%)
occurrences causally related to treatment / all	1 / 39	0 / 36
deaths causally related to treatment / all	0 / 0	0 / 0
Cor pulmonale		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery stenosis		
subjects affected / exposed	7 / 4229 (0.17%)	5 / 4203 (0.12%)
occurrences causally related to treatment / all	0 / 7	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery occlusion		
subjects affected / exposed	1 / 4229 (0.02%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	1 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Defect conduction intraventricular		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dilatation atrial		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery thrombosis		

subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dilatation ventricular		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrocardiac syndrome		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertensive cardiomyopathy		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertensive heart disease		
subjects affected / exposed	2 / 4229 (0.05%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Left ventricular dysfunction		
subjects affected / exposed	6 / 4229 (0.14%)	6 / 4203 (0.14%)
occurrences causally related to treatment / all	0 / 6	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Ischaemic cardiomyopathy		
subjects affected / exposed	14 / 4229 (0.33%)	5 / 4203 (0.12%)
occurrences causally related to treatment / all	0 / 16	3 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Left ventricular failure		
subjects affected / exposed	2 / 4229 (0.05%)	9 / 4203 (0.21%)
occurrences causally related to treatment / all	0 / 2	1 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Low cardiac output syndrome		

subjects affected / exposed	2 / 4229 (0.05%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Mitral valve disease</b>		
subjects affected / exposed	2 / 4229 (0.05%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Mitral valve disease mixed</b>		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Mitral valve incompetence</b>		
subjects affected / exposed	13 / 4229 (0.31%)	10 / 4203 (0.24%)
occurrences causally related to treatment / all	0 / 14	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Myocardial ischaemia</b>		
subjects affected / exposed	29 / 4229 (0.69%)	20 / 4203 (0.48%)
occurrences causally related to treatment / all	3 / 29	0 / 20
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Myocardial infarction</b>		
subjects affected / exposed	72 / 4229 (1.70%)	65 / 4203 (1.55%)
occurrences causally related to treatment / all	1 / 79	0 / 70
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Myocarditis</b>		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Nodal arrhythmia</b>		
subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Nodal rhythm</b>		

subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Palpitations</b>		
subjects affected / exposed	8 / 4229 (0.19%)	3 / 4203 (0.07%)
occurrences causally related to treatment / all	0 / 8	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pericardial effusion</b>		
subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pulseless electrical activity</b>		
subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Right ventricular failure</b>		
subjects affected / exposed	4 / 4229 (0.09%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Right ventricular dysfunction</b>		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Sick sinus syndrome</b>		
subjects affected / exposed	9 / 4229 (0.21%)	10 / 4203 (0.24%)
occurrences causally related to treatment / all	0 / 9	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Silent myocardial infarction</b>		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Sinus bradycardia</b>		

subjects affected / exposed	3 / 4229 (0.07%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Sinus tachycardia		
subjects affected / exposed	2 / 4229 (0.05%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Systolic dysfunction		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Supraventricular tachycardia		
subjects affected / exposed	9 / 4229 (0.21%)	9 / 4203 (0.21%)
occurrences causally related to treatment / all	0 / 9	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Tachyarrhythmia		
subjects affected / exposed	3 / 4229 (0.07%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tachycardia		
subjects affected / exposed	5 / 4229 (0.12%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Torsade de pointes		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tricuspid valve incompetence		
subjects affected / exposed	2 / 4229 (0.05%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Trifascicular block		

subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ventricular dysfunction		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ventricular arrhythmia		
subjects affected / exposed	11 / 4229 (0.26%)	5 / 4203 (0.12%)
occurrences causally related to treatment / all	0 / 12	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Ventricular dyssynchrony		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ventricular extrasystoles		
subjects affected / exposed	4 / 4229 (0.09%)	6 / 4203 (0.14%)
occurrences causally related to treatment / all	0 / 5	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Ventricular fibrillation		
subjects affected / exposed	28 / 4229 (0.66%)	22 / 4203 (0.52%)
occurrences causally related to treatment / all	2 / 28	0 / 22
deaths causally related to treatment / all	0 / 0	0 / 0
Ventricular flutter		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ventricular hypokinesia		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ventricular tachyarrhythmia		

subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular tachycardia			
subjects affected / exposed	85 / 4229 (2.01%)	66 / 4203 (1.57%)	
occurrences causally related to treatment / all	8 / 114	1 / 90	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Amnesia			
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aphasia			
subjects affected / exposed	0 / 4229 (0.00%)	2 / 4203 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ataxia			
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Basilar artery thrombosis			
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain hypoxia			
subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain injury			
subjects affected / exposed	1 / 4229 (0.02%)	2 / 4203 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain mass			

subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Brain oedema</b>		
subjects affected / exposed	4 / 4229 (0.09%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Brain stem infarction</b>		
subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Carotid artery disease</b>		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Carotid artery stenosis</b>		
subjects affected / exposed	2 / 4229 (0.05%)	4 / 4203 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Carpal tunnel syndrome</b>		
subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cerebellar atrophy</b>		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cerebellar infarction</b>		
subjects affected / exposed	1 / 4229 (0.02%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cerebral atrophy</b>		

subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral haemorrhage		
subjects affected / exposed	6 / 4229 (0.14%)	5 / 4203 (0.12%)
occurrences causally related to treatment / all	0 / 6	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral haematoma		
subjects affected / exposed	3 / 4229 (0.07%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral ischaemia		
subjects affected / exposed	2 / 4229 (0.05%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral venous thrombosis		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral infarction		
subjects affected / exposed	13 / 4229 (0.31%)	8 / 4203 (0.19%)
occurrences causally related to treatment / all	0 / 13	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebrovascular disorder		
subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebrovascular accident		
subjects affected / exposed	72 / 4229 (1.70%)	71 / 4203 (1.69%)
occurrences causally related to treatment / all	1 / 75	1 / 76
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebrovascular insufficiency		

subjects affected / exposed	1 / 4229 (0.02%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Coma		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Convulsion		
subjects affected / exposed	7 / 4229 (0.17%)	5 / 4203 (0.12%)
occurrences causally related to treatment / all	0 / 7	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Convulsions local		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dementia		
subjects affected / exposed	2 / 4229 (0.05%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Dementia Alzheimer's type		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Depressed level of consciousness		
subjects affected / exposed	2 / 4229 (0.05%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dizziness		
subjects affected / exposed	5 / 4229 (0.12%)	10 / 4203 (0.24%)
occurrences causally related to treatment / all	1 / 5	2 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic coma		

subjects affected / exposed	0 / 4229 (0.00%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic neuropathy		
subjects affected / exposed	2 / 4229 (0.05%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Dysarthria		
subjects affected / exposed	3 / 4229 (0.07%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Embolic stroke		
subjects affected / exposed	6 / 4229 (0.14%)	3 / 4203 (0.07%)
occurrences causally related to treatment / all	0 / 6	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Epilepsy		
subjects affected / exposed	1 / 4229 (0.02%)	3 / 4203 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Encephalomalacia		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Guillain-Barre syndrome		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhage intracranial		
subjects affected / exposed	0 / 4229 (0.00%)	4 / 4203 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhagic stroke		

subjects affected / exposed	5 / 4229 (0.12%)	5 / 4203 (0.12%)
occurrences causally related to treatment / all	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Headache		
subjects affected / exposed	0 / 4229 (0.00%)	3 / 4203 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhagic transformation stroke		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hemiparesis		
subjects affected / exposed	1 / 4229 (0.02%)	3 / 4203 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Hemiplegia		
subjects affected / exposed	3 / 4229 (0.07%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hemisensory neglect		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic encephalopathy		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hydrocephalus		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypercapnic coma		

subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperaesthesia		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoglycaemic coma		
subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoaesthesia		
subjects affected / exposed	2 / 4229 (0.05%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoglycaemic seizure		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoxic-ischaemic encephalopathy		
subjects affected / exposed	2 / 4229 (0.05%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intercostal neuralgia		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ischaemic neuropathy		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lacunar infarction		

subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Ischaemic stroke</b>		
subjects affected / exposed	37 / 4229 (0.87%)	40 / 4203 (0.95%)
occurrences causally related to treatment / all	2 / 38	0 / 42
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Lethargy</b>		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Mental retardation</b>		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Loss of consciousness</b>		
subjects affected / exposed	4 / 4229 (0.09%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	2 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Motor dysfunction</b>		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Metabolic encephalopathy</b>		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Movement disorder</b>		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Multiple system atrophy</b>		

subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neuralgia		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Neuropathy peripheral		
subjects affected / exposed	3 / 4229 (0.07%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Paraparesis		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Parkinson's disease		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Partial seizures		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral sensory neuropathy		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Polyneuropathy		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Presenile dementia		

subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Presyncope		
subjects affected / exposed	7 / 4229 (0.17%)	5 / 4203 (0.12%)
occurrences causally related to treatment / all	1 / 8	1 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Radiculopathy		
subjects affected / exposed	0 / 4229 (0.00%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Reversible ischaemic neurological deficit		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sciatica		
subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Subarachnoid haemorrhage		
subjects affected / exposed	5 / 4229 (0.12%)	3 / 4203 (0.07%)
occurrences causally related to treatment / all	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Syncope		
subjects affected / exposed	68 / 4229 (1.61%)	43 / 4203 (1.02%)
occurrences causally related to treatment / all	11 / 75	5 / 47
deaths causally related to treatment / all	0 / 0	0 / 0
Tension headache		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Toxic encephalopathy		

subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transient ischaemic attack			
subjects affected / exposed	22 / 4229 (0.52%)	18 / 4203 (0.43%)	
occurrences causally related to treatment / all	0 / 23	0 / 20	
deaths causally related to treatment / all	0 / 0	0 / 0	
VIIth nerve paralysis			
subjects affected / exposed	2 / 4229 (0.05%)	0 / 4203 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebral artery stenosis			
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebrobasilar insufficiency			
subjects affected / exposed	1 / 4229 (0.02%)	4 / 4203 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vocal cord paralysis			
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	47 / 4229 (1.11%)	31 / 4203 (0.74%)	
occurrences causally related to treatment / all	0 / 54	0 / 37	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia of malignant disease			
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Autoimmune haemolytic anaemia			

subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Anaemia macrocytic		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Coagulopathy		
subjects affected / exposed	2 / 4229 (0.05%)	3 / 4203 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Disseminated intravascular coagulation		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhagic anaemia		
subjects affected / exposed	3 / 4229 (0.07%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhagic disorder		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypochromic anaemia		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Immune thrombocytopenic purpura		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Iron deficiency anaemia		

subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Leukocytosis		
subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Leukopenia		
subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphadenopathy		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Microcytic anaemia		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nephrogenic anaemia		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neutropenia		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Normochromic normocytic anaemia		
subjects affected / exposed	2 / 4229 (0.05%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pancytopenia		

subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pernicious anaemia			
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spontaneous haematoma			
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombocytopenia			
subjects affected / exposed	4 / 4229 (0.09%)	4 / 4203 (0.10%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
Acute vestibular syndrome			
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deafness neurosensory			
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deafness unilateral			
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear haemorrhage			
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mastoid disorder			

subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tinnitus			
subjects affected / exposed	0 / 4229 (0.00%)	2 / 4203 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo			
subjects affected / exposed	9 / 4229 (0.21%)	5 / 4203 (0.12%)	
occurrences causally related to treatment / all	0 / 10	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo positional			
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Amaurosis fugax			
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blindness unilateral			
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cataract			
subjects affected / exposed	8 / 4229 (0.19%)	12 / 4203 (0.29%)	
occurrences causally related to treatment / all	0 / 9	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cataract diabetic			
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Conjunctival haemorrhage			

subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic retinopathy		
subjects affected / exposed	1 / 4229 (0.02%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Diplopia		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Glaucoma		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Macular oedema		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Retinal artery embolism		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Retinal detachment		
subjects affected / exposed	2 / 4229 (0.05%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Retinal haemorrhage		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Trichiasis		

subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vitreous haemorrhage			
subjects affected / exposed	2 / 4229 (0.05%)	0 / 4203 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vision blurred			
subjects affected / exposed	0 / 4229 (0.00%)	2 / 4203 (0.05%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal compartment syndrome			
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal adhesions			
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal discomfort			
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal distension			
subjects affected / exposed	3 / 4229 (0.07%)	4 / 4203 (0.10%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal hernia			
subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain			

subjects affected / exposed	23 / 4229 (0.54%)	15 / 4203 (0.36%)
occurrences causally related to treatment / all	1 / 26	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal pain upper		
subjects affected / exposed	7 / 4229 (0.17%)	6 / 4203 (0.14%)
occurrences causally related to treatment / all	0 / 7	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal wall haematoma		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Acute abdomen		
subjects affected / exposed	3 / 4229 (0.07%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Anal fissure		
subjects affected / exposed	1 / 4229 (0.02%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Anal fistula		
subjects affected / exposed	0 / 4229 (0.00%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Anal haemorrhage		
subjects affected / exposed	2 / 4229 (0.05%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Anorectal discomfort		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ascites		

subjects affected / exposed	6 / 4229 (0.14%)	5 / 4203 (0.12%)
occurrences causally related to treatment / all	0 / 6	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Colitis		
subjects affected / exposed	3 / 4229 (0.07%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Colitis ischaemic		
subjects affected / exposed	4 / 4229 (0.09%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Colitis ulcerative		
subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Constipation		
subjects affected / exposed	5 / 4229 (0.12%)	3 / 4203 (0.07%)
occurrences causally related to treatment / all	1 / 7	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Crohn's disease		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dental caries		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diarrhoea		
subjects affected / exposed	15 / 4229 (0.35%)	22 / 4203 (0.52%)
occurrences causally related to treatment / all	2 / 15	1 / 22
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulum		

subjects affected / exposed	0 / 4229 (0.00%)	3 / 4203 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulum intestinal		
subjects affected / exposed	2 / 4229 (0.05%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenal stenosis		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenal ulcer		
subjects affected / exposed	9 / 4229 (0.21%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 9	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenal ulcer haemorrhage		
subjects affected / exposed	3 / 4229 (0.07%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenitis		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenal ulcer perforation		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dyspepsia		
subjects affected / exposed	4 / 4229 (0.09%)	3 / 4203 (0.07%)
occurrences causally related to treatment / all	0 / 4	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Dysphagia		

subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Enteritis		
subjects affected / exposed	2 / 4229 (0.05%)	3 / 4203 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Enterovesical fistula		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Erosive duodenitis		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Faecal incontinence		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Erosive oesophagitis		
subjects affected / exposed	3 / 4229 (0.07%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Faecaloma		
subjects affected / exposed	0 / 4229 (0.00%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Femoral hernia		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric haemorrhage		

subjects affected / exposed	3 / 4229 (0.07%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric hypomotility		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric perforation		
subjects affected / exposed	2 / 4229 (0.05%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric polyps		
subjects affected / exposed	3 / 4229 (0.07%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric ulcer haemorrhage		
subjects affected / exposed	2 / 4229 (0.05%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric ulcer		
subjects affected / exposed	3 / 4229 (0.07%)	3 / 4203 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Gastritis		
subjects affected / exposed	10 / 4229 (0.24%)	7 / 4203 (0.17%)
occurrences causally related to treatment / all	0 / 10	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Gastritis erosive		
subjects affected / exposed	4 / 4229 (0.09%)	3 / 4203 (0.07%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroduodenal haemorrhage		

subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastritis haemorrhagic		
subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal disorder		
subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroduodenitis		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal haemorrhage		
subjects affected / exposed	22 / 4229 (0.52%)	22 / 4203 (0.52%)
occurrences causally related to treatment / all	0 / 22	1 / 26
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal necrosis		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal obstruction		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal ulcer		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrooesophageal reflux disease		

subjects affected / exposed	6 / 4229 (0.14%)	4 / 4203 (0.10%)
occurrences causally related to treatment / all	0 / 6	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Haematemesis</b>		
subjects affected / exposed	3 / 4229 (0.07%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Haemorrhagic erosive gastritis</b>		
subjects affected / exposed	2 / 4229 (0.05%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	2 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Haematochezia</b>		
subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Haemorrhoidal haemorrhage</b>		
subjects affected / exposed	1 / 4229 (0.02%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Haemorrhoids</b>		
subjects affected / exposed	2 / 4229 (0.05%)	4 / 4203 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hiatus hernia</b>		
subjects affected / exposed	3 / 4229 (0.07%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hyperchlorhydria</b>		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Ileus paralytic</b>		

subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ileus		
subjects affected / exposed	2 / 4229 (0.05%)	5 / 4203 (0.12%)
occurrences causally related to treatment / all	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Impaired gastric emptying		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Inguinal hernia		
subjects affected / exposed	17 / 4229 (0.40%)	11 / 4203 (0.26%)
occurrences causally related to treatment / all	0 / 17	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Inguinal hernia strangulated		
subjects affected / exposed	2 / 4229 (0.05%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal haemorrhage		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Inguinal hernia, obstructive		
subjects affected / exposed	3 / 4229 (0.07%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal obstruction		
subjects affected / exposed	5 / 4229 (0.12%)	4 / 4203 (0.10%)
occurrences causally related to treatment / all	0 / 8	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal ischaemia		

subjects affected / exposed	1 / 4229 (0.02%)	5 / 4203 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal perforation		
subjects affected / exposed	2 / 4229 (0.05%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal polyp		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intra-abdominal haemorrhage		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Large intestinal haemorrhage		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Large intestine perforation		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Large intestine polyp		
subjects affected / exposed	2 / 4229 (0.05%)	5 / 4203 (0.12%)
occurrences causally related to treatment / all	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Lip oedema		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lower gastrointestinal haemorrhage		

subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Mallory-Weiss syndrome</b>		
subjects affected / exposed	2 / 4229 (0.05%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Melaena</b>		
subjects affected / exposed	5 / 4229 (0.12%)	3 / 4203 (0.07%)
occurrences causally related to treatment / all	1 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Mouth haemorrhage</b>		
subjects affected / exposed	2 / 4229 (0.05%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Nausea</b>		
subjects affected / exposed	6 / 4229 (0.14%)	6 / 4203 (0.14%)
occurrences causally related to treatment / all	2 / 6	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Obstruction gastric</b>		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Oesophageal achalasia</b>		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Oesophageal ulcer</b>		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Oesophageal ulcer haemorrhage</b>		

subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Oesophagitis</b>		
subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pancreatitis</b>		
subjects affected / exposed	8 / 4229 (0.19%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 8	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pancreatitis acute</b>		
subjects affected / exposed	4 / 4229 (0.09%)	7 / 4203 (0.17%)
occurrences causally related to treatment / all	2 / 6	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pancreatitis chronic</b>		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Parotid gland enlargement</b>		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Parotid duct obstruction</b>		
subjects affected / exposed	2 / 4229 (0.05%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Peptic ulcer</b>		
subjects affected / exposed	1 / 4229 (0.02%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Peptic ulcer perforation</b>		

subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Portal hypertensive gastropathy		
subjects affected / exposed	2 / 4229 (0.05%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal haemorrhage		
subjects affected / exposed	3 / 4229 (0.07%)	8 / 4203 (0.19%)
occurrences causally related to treatment / all	1 / 3	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Proctalgia		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal polyp		
subjects affected / exposed	1 / 4229 (0.02%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal prolapse		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal stenosis		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Retroperitoneal haematoma		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Small intestinal obstruction		

subjects affected / exposed	3 / 4229 (0.07%)	3 / 4203 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Retroperitoneal haemorrhage</b>		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Stomatitis</b>		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Subileus</b>		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Toothache</b>		
subjects affected / exposed	1 / 4229 (0.02%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Umbilical hernia, obstructive</b>		
subjects affected / exposed	1 / 4229 (0.02%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Umbilical hernia</b>		
subjects affected / exposed	6 / 4229 (0.14%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Upper gastrointestinal haemorrhage</b>		
subjects affected / exposed	6 / 4229 (0.14%)	9 / 4203 (0.21%)
occurrences causally related to treatment / all	0 / 7	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Varices oesophageal</b>		

subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	14 / 4229 (0.33%)	10 / 4203 (0.24%)	
occurrences causally related to treatment / all	1 / 15	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Angioedema			
subjects affected / exposed	4 / 4229 (0.09%)	3 / 4203 (0.07%)	
occurrences causally related to treatment / all	3 / 4	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angiokeratoma			
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cutaneous vasculitis			
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Decubitus ulcer			
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermatitis			
subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermatitis allergic			
subjects affected / exposed	0 / 4229 (0.00%)	2 / 4203 (0.05%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermatitis contact			

subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic foot		
subjects affected / exposed	7 / 4229 (0.17%)	7 / 4203 (0.17%)
occurrences causally related to treatment / all	0 / 11	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Hypersensitivity vasculitis		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperhidrosis		
subjects affected / exposed	2 / 4229 (0.05%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lichen planus		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pemphigoid		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pemphigus		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Penile ulceration		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Psoriasis		

subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Rash</b>		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Skin burning sensation</b>		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Skin erosion</b>		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Skin necrosis</b>		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Skin ulcer</b>		
subjects affected / exposed	6 / 4229 (0.14%)	3 / 4203 (0.07%)
occurrences causally related to treatment / all	0 / 6	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Skin ulcer haemorrhage</b>		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Stasis dermatitis</b>		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Urticaria</b>		

subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Renal and urinary disorders</b>			
<b>Acute prerenal failure</b>			
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Azotaemia</b>			
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Calculus ureteric</b>			
subjects affected / exposed	0 / 4229 (0.00%)	2 / 4203 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Bladder diverticulum</b>			
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Crush syndrome</b>			
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Cystitis erosive</b>			
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Diabetic nephropathy</b>			
subjects affected / exposed	2 / 4229 (0.05%)	0 / 4203 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Cystitis haemorrhagic</b>			

subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cystitis noninfective		
subjects affected / exposed	2 / 4229 (0.05%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Haematuria		
subjects affected / exposed	10 / 4229 (0.24%)	14 / 4203 (0.33%)
occurrences causally related to treatment / all	0 / 11	0 / 16
deaths causally related to treatment / all	0 / 0	0 / 0
Dysuria		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Incontinence		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hydronephrosis		
subjects affected / exposed	3 / 4229 (0.07%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Kidney fibrosis		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lower urinary tract symptoms		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nephrolithiasis		

subjects affected / exposed	4 / 4229 (0.09%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Nephropathy</b>		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Nephropathy toxic</b>		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Nephrotic syndrome</b>		
subjects affected / exposed	2 / 4229 (0.05%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Nephrosclerosis</b>		
subjects affected / exposed	0 / 4229 (0.00%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Oliguria</b>		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Prerenal failure</b>		
subjects affected / exposed	3 / 4229 (0.07%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pelvi-ureteric obstruction</b>		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Proteinuria</b>		

subjects affected / exposed	0 / 4229 (0.00%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Renal aneurysm		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renal colic		
subjects affected / exposed	1 / 4229 (0.02%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Renal cyst		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal failure		
subjects affected / exposed	54 / 4229 (1.28%)	43 / 4203 (1.02%)
occurrences causally related to treatment / all	13 / 62	10 / 44
deaths causally related to treatment / all	0 / 0	0 / 0
Renal failure acute		
subjects affected / exposed	79 / 4229 (1.87%)	74 / 4203 (1.76%)
occurrences causally related to treatment / all	11 / 89	17 / 80
deaths causally related to treatment / all	0 / 0	0 / 0
Renal failure chronic		
subjects affected / exposed	13 / 4229 (0.31%)	9 / 4203 (0.21%)
occurrences causally related to treatment / all	1 / 14	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Renal injury		
subjects affected / exposed	0 / 4229 (0.00%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Renal impairment		

subjects affected / exposed	57 / 4229 (1.35%)	46 / 4203 (1.09%)	
occurrences causally related to treatment / all	17 / 59	14 / 49	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal tubular acidosis			
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal tubular necrosis			
subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tubulointerstitial nephritis			
subjects affected / exposed	3 / 4229 (0.07%)	0 / 4203 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urethral stenosis			
subjects affected / exposed	1 / 4229 (0.02%)	2 / 4203 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary incontinence			
subjects affected / exposed	2 / 4229 (0.05%)	0 / 4203 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urine flow decreased			
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary retention			
subjects affected / exposed	8 / 4229 (0.19%)	10 / 4203 (0.24%)	
occurrences causally related to treatment / all	0 / 9	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Autoimmune thyroiditis			

subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Goitre</b>			
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Hyperthyroidism</b>			
subjects affected / exposed	3 / 4229 (0.07%)	3 / 4203 (0.07%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Hypothyroidism</b>			
subjects affected / exposed	4 / 4229 (0.09%)	1 / 4203 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Thyroiditis subacute</b>			
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Musculoskeletal and connective tissue disorders</b>			
<b>Arthralgia</b>			
subjects affected / exposed	2 / 4229 (0.05%)	3 / 4203 (0.07%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Arthritis</b>			
subjects affected / exposed	2 / 4229 (0.05%)	0 / 4203 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Back pain</b>			
subjects affected / exposed	1 / 4229 (0.02%)	7 / 4203 (0.17%)	
occurrences causally related to treatment / all	0 / 1	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Compartment syndrome</b>			

subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dupuytren's contracture		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Costochondritis		
subjects affected / exposed	2 / 4229 (0.05%)	3 / 4203 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Flank pain		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Foot deformity		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gouty arthritis		
subjects affected / exposed	2 / 4229 (0.05%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haemarthrosis		
subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral disc degeneration		
subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral disc displacement		

subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Intervertebral disc disorder</b>		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Joint laxity</b>		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Intervertebral disc protrusion</b>		
subjects affected / exposed	2 / 4229 (0.05%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Joint effusion</b>		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Lumbar spinal stenosis</b>		
subjects affected / exposed	1 / 4229 (0.02%)	3 / 4203 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Joint swelling</b>		
subjects affected / exposed	1 / 4229 (0.02%)	3 / 4203 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Mobility decreased</b>		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Muscle fatigue</b>		

subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Muscle necrosis</b>		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Muscle swelling</b>		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Muscular weakness</b>		
subjects affected / exposed	4 / 4229 (0.09%)	3 / 4203 (0.07%)
occurrences causally related to treatment / all	1 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Musculoskeletal chest pain</b>		
subjects affected / exposed	5 / 4229 (0.12%)	4 / 4203 (0.10%)
occurrences causally related to treatment / all	0 / 7	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Musculoskeletal pain</b>		
subjects affected / exposed	1 / 4229 (0.02%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Myalgia</b>		
subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Myalgia intercostal</b>		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Osteitis</b>		

subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Osteochondrosis</b>		
subjects affected / exposed	2 / 4229 (0.05%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Osteoarthritis</b>		
subjects affected / exposed	15 / 4229 (0.35%)	16 / 4203 (0.38%)
occurrences causally related to treatment / all	0 / 16	0 / 17
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Osteonecrosis</b>		
subjects affected / exposed	2 / 4229 (0.05%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Osteoporotic fracture</b>		
subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pathological fracture</b>		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Periarthritis</b>		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pain in extremity</b>		
subjects affected / exposed	3 / 4229 (0.07%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Rheumatoid arthritis</b>		

subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Rhabdomyolysis</b>		
subjects affected / exposed	2 / 4229 (0.05%)	4 / 4203 (0.10%)
occurrences causally related to treatment / all	1 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Rotator cuff syndrome</b>		
subjects affected / exposed	3 / 4229 (0.07%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Spinal column stenosis</b>		
subjects affected / exposed	3 / 4229 (0.07%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Spinal osteoarthritis</b>		
subjects affected / exposed	0 / 4229 (0.00%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Spinal pain</b>		
subjects affected / exposed	1 / 4229 (0.02%)	3 / 4203 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Synovitis</b>		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Tendonitis</b>		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Synovial cyst</b>		

subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Trigger finger			
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal wall abscess			
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal wall infection			
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess limb			
subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess neck			
subjects affected / exposed	2 / 4229 (0.05%)	1 / 4203 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess oral			
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acinetobacter bacteraemia			

subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Acinetobacter infection		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Acute endocarditis		
subjects affected / exposed	2 / 4229 (0.05%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Acute tonsillitis		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
American trypanosomiasis		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Anal abscess		
subjects affected / exposed	3 / 4229 (0.07%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Appendicitis		
subjects affected / exposed	6 / 4229 (0.14%)	5 / 4203 (0.12%)
occurrences causally related to treatment / all	0 / 6	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Appendicitis perforated		
subjects affected / exposed	1 / 4229 (0.02%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Arthritis infective		

subjects affected / exposed	2 / 4229 (0.05%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Arthritis bacterial</b>		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Atypical pneumonia</b>		
subjects affected / exposed	1 / 4229 (0.02%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bacterial diarrhoea</b>		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bacteraemia</b>		
subjects affected / exposed	0 / 4229 (0.00%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bacterial prostatitis</b>		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bacterial infection</b>		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bacterial sepsis</b>		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bacterial tracheitis</b>		

subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bacteriuria</b>		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Biliary sepsis</b>		
subjects affected / exposed	1 / 4229 (0.02%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Breast cellulitis</b>		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bronchiolitis</b>		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bronchitis bacterial</b>		
subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bronchitis</b>		
subjects affected / exposed	26 / 4229 (0.61%)	20 / 4203 (0.48%)
occurrences causally related to treatment / all	0 / 27	0 / 23
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bronchitis fungal</b>		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bronchitis viral</b>		

subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bronchopneumonia</b>		
subjects affected / exposed	14 / 4229 (0.33%)	21 / 4203 (0.50%)
occurrences causally related to treatment / all	0 / 15	0 / 22
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Campylobacter gastroenteritis</b>		
subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cellulitis</b>		
subjects affected / exposed	23 / 4229 (0.54%)	19 / 4203 (0.45%)
occurrences causally related to treatment / all	0 / 24	0 / 20
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Carbuncle</b>		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cellulitis staphylococcal</b>		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cholecystitis infective</b>		
subjects affected / exposed	0 / 4229 (0.00%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Chronic hepatitis B</b>		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Clostridial infection</b>		

subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Clostridium difficile colitis</b>		
subjects affected / exposed	2 / 4229 (0.05%)	3 / 4203 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Clostridium difficile infection</b>		
subjects affected / exposed	3 / 4229 (0.07%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cytomegalovirus infection</b>		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cystitis</b>		
subjects affected / exposed	5 / 4229 (0.12%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 6	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Dacryocanaliculitis</b>		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Dermatophytosis</b>		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Device related infection</b>		
subjects affected / exposed	11 / 4229 (0.26%)	10 / 4203 (0.24%)
occurrences causally related to treatment / all	0 / 11	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Diabetic foot infection</b>		

subjects affected / exposed	1 / 4229 (0.02%)	2 / 4203 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device related sepsis			
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic gangrene			
subjects affected / exposed	0 / 4229 (0.00%)	2 / 4203 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea infectious			
subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Disseminated tuberculosis			
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulitis			
subjects affected / exposed	3 / 4229 (0.07%)	2 / 4203 (0.05%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Encephalitis			
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Empyema			
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Encephalitis viral			

subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Endocarditis		
subjects affected / exposed	8 / 4229 (0.19%)	4 / 4203 (0.10%)
occurrences causally related to treatment / all	0 / 8	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Endocarditis bacterial		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Epididymitis		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Erysipelas		
subjects affected / exposed	11 / 4229 (0.26%)	10 / 4203 (0.24%)
occurrences causally related to treatment / all	0 / 12	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0
Escherichia sepsis		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Escherichia urinary tract infection		
subjects affected / exposed	2 / 4229 (0.05%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gallbladder abscess		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gangrene		

subjects affected / exposed	12 / 4229 (0.28%)	8 / 4203 (0.19%)
occurrences causally related to treatment / all	0 / 12	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis		
subjects affected / exposed	22 / 4229 (0.52%)	22 / 4203 (0.52%)
occurrences causally related to treatment / all	1 / 23	1 / 23
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis clostridial		
subjects affected / exposed	0 / 4229 (0.00%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis norovirus		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis viral		
subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal bacterial infection		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal infection		
subjects affected / exposed	2 / 4229 (0.05%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal viral infection		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Groin abscess		

subjects affected / exposed	0 / 4229 (0.00%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
H1N1 influenza		
subjects affected / exposed	2 / 4229 (0.05%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Haematoma infection		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhagic fever		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatitis A		
subjects affected / exposed	2 / 4229 (0.05%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Herpes simplex meningoencephalitis		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatitis B		
subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Herpes zoster		
subjects affected / exposed	3 / 4229 (0.07%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Implant site infection		

subjects affected / exposed	1 / 4229 (0.02%)	3 / 4203 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Infected cyst		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Infected dermal cyst		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Infected skin ulcer		
subjects affected / exposed	3 / 4229 (0.07%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Infective exacerbation of bronchiectasis		
subjects affected / exposed	2 / 4229 (0.05%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Infectious pleural effusion		
subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Infective exacerbation of chronic obstructive airways disease		
subjects affected / exposed	3 / 4229 (0.07%)	5 / 4203 (0.12%)
occurrences causally related to treatment / all	0 / 3	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral discitis		
subjects affected / exposed	0 / 4229 (0.00%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Influenza		

subjects affected / exposed	5 / 4229 (0.12%)	5 / 4203 (0.12%)
occurrences causally related to treatment / all	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Kidney infection</b>		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Joint abscess</b>		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Labyrinthitis</b>		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Laryngitis</b>		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Liver abscess</b>		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Lobar pneumonia</b>		
subjects affected / exposed	6 / 4229 (0.14%)	5 / 4203 (0.12%)
occurrences causally related to treatment / all	0 / 6	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Localised infection</b>		
subjects affected / exposed	2 / 4229 (0.05%)	4 / 4203 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Lower respiratory tract infection</b>		

subjects affected / exposed	21 / 4229 (0.50%)	13 / 4203 (0.31%)
occurrences causally related to treatment / all	0 / 22	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0
Lower respiratory tract infection bacterial		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lung infection		
subjects affected / exposed	12 / 4229 (0.28%)	6 / 4203 (0.14%)
occurrences causally related to treatment / all	0 / 13	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Lower respiratory tract infection viral		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Meningitis		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Morganella infection		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Myocarditis infectious		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Nasopharyngitis		
subjects affected / exposed	2 / 4229 (0.05%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Necrotising fasciitis		

subjects affected / exposed	0 / 4229 (0.00%)	3 / 4203 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Osteomyelitis</b>		
subjects affected / exposed	2 / 4229 (0.05%)	7 / 4203 (0.17%)
occurrences causally related to treatment / all	0 / 2	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Orchitis</b>		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Otitis media</b>		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Parotitis</b>		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Perineal abscess</b>		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Peritoneal abscess</b>		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Peritonitis</b>		
subjects affected / exposed	2 / 4229 (0.05%)	6 / 4203 (0.14%)
occurrences causally related to treatment / all	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pharyngitis</b>		

subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumococcal sepsis		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia		
subjects affected / exposed	181 / 4229 (4.28%)	155 / 4203 (3.69%)
occurrences causally related to treatment / all	3 / 224	0 / 185
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia bacterial		
subjects affected / exposed	1 / 4229 (0.02%)	3 / 4203 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia haemophilus		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia klebsiella		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia influenzal		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia pneumococcal		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia legionella		

subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia staphylococcal		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia viral		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural infection		
subjects affected / exposed	0 / 4229 (0.00%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural pneumonia		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative wound infection		
subjects affected / exposed	3 / 4229 (0.07%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pseudomembranous colitis		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary tuberculosis		
subjects affected / exposed	2 / 4229 (0.05%)	5 / 4203 (0.12%)
occurrences causally related to treatment / all	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary sepsis		

subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pyelonephritis		
subjects affected / exposed	2 / 4229 (0.05%)	3 / 4203 (0.07%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Pyelonephritis acute		
subjects affected / exposed	3 / 4229 (0.07%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pyelonephritis chronic		
subjects affected / exposed	1 / 4229 (0.02%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Rabies		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory syncytial virus infection		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal abscess		
subjects affected / exposed	2 / 4229 (0.05%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory tract infection		
subjects affected / exposed	8 / 4229 (0.19%)	15 / 4203 (0.36%)
occurrences causally related to treatment / all	0 / 8	0 / 18
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory tract infection bacterial		

subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Salmonellosis</b>		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Scrotal infection</b>		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Scrotal gangrene</b>		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Sepsis</b>		
subjects affected / exposed	37 / 4229 (0.87%)	24 / 4203 (0.57%)
occurrences causally related to treatment / all	1 / 38	0 / 26
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Septic shock</b>		
subjects affected / exposed	23 / 4229 (0.54%)	17 / 4203 (0.40%)
occurrences causally related to treatment / all	0 / 23	0 / 17
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Sinusitis</b>		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Skin bacterial infection</b>		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Soft tissue infection</b>		

subjects affected / exposed	2 / 4229 (0.05%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Staphylococcal bacteraemia		
subjects affected / exposed	2 / 4229 (0.05%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Staphylococcal abscess		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Staphylococcal infection		
subjects affected / exposed	4 / 4229 (0.09%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Staphylococcal sepsis		
subjects affected / exposed	0 / 4229 (0.00%)	4 / 4203 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Stoma site infection		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Streptococcal bacteraemia		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Subcutaneous abscess		
subjects affected / exposed	2 / 4229 (0.05%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tooth abscess		

subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tracheobronchitis		
subjects affected / exposed	3 / 4229 (0.07%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Tooth infection		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tuberculosis		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tuberculous pleurisy		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Upper respiratory tract infection		
subjects affected / exposed	11 / 4229 (0.26%)	6 / 4203 (0.14%)
occurrences causally related to treatment / all	0 / 12	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary tract infection		
subjects affected / exposed	34 / 4229 (0.80%)	41 / 4203 (0.98%)
occurrences causally related to treatment / all	0 / 37	0 / 46
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary tract infection bacterial		
subjects affected / exposed	2 / 4229 (0.05%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Urosepsis		

subjects affected / exposed	9 / 4229 (0.21%)	8 / 4203 (0.19%)	
occurrences causally related to treatment / all	0 / 9	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vestibular neuronitis			
subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viraemia			
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral infection			
subjects affected / exposed	4 / 4229 (0.09%)	1 / 4203 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral myocarditis			
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral upper respiratory tract infection			
subjects affected / exposed	2 / 4229 (0.05%)	0 / 4203 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound abscess			
subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound sepsis			
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Cachexia			

subjects affected / exposed	1 / 4229 (0.02%)	3 / 4203 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetes mellitus		
subjects affected / exposed	23 / 4229 (0.54%)	24 / 4203 (0.57%)
occurrences causally related to treatment / all	0 / 23	0 / 24
deaths causally related to treatment / all	0 / 0	0 / 0
Dehydration		
subjects affected / exposed	29 / 4229 (0.69%)	22 / 4203 (0.52%)
occurrences causally related to treatment / all	1 / 30	0 / 22
deaths causally related to treatment / all	0 / 0	0 / 0
Decreased appetite		
subjects affected / exposed	5 / 4229 (0.12%)	4 / 4203 (0.10%)
occurrences causally related to treatment / all	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic ketoacidosis		
subjects affected / exposed	4 / 4229 (0.09%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetes mellitus inadequate control		
subjects affected / exposed	8 / 4229 (0.19%)	7 / 4203 (0.17%)
occurrences causally related to treatment / all	0 / 9	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Electrolyte imbalance		
subjects affected / exposed	2 / 4229 (0.05%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	1 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Fluid overload		
subjects affected / exposed	2 / 4229 (0.05%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Failure to thrive		

subjects affected / exposed	0 / 4229 (0.00%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperglycaemia		
subjects affected / exposed	4 / 4229 (0.09%)	6 / 4203 (0.14%)
occurrences causally related to treatment / all	0 / 4	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Gout		
subjects affected / exposed	10 / 4229 (0.24%)	7 / 4203 (0.17%)
occurrences causally related to treatment / all	1 / 11	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperglycaemic hyperosmolar nonketotic syndrome		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperkalaemia		
subjects affected / exposed	42 / 4229 (0.99%)	17 / 4203 (0.40%)
occurrences causally related to treatment / all	17 / 46	13 / 18
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperuricaemia		
subjects affected / exposed	2 / 4229 (0.05%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypocalcaemia		
subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hypervolaemia		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypochloraemia		

subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoglycaemia		
subjects affected / exposed	14 / 4229 (0.33%)	15 / 4203 (0.36%)
occurrences causally related to treatment / all	0 / 14	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0
Hypokalaemia		
subjects affected / exposed	9 / 4229 (0.21%)	12 / 4203 (0.29%)
occurrences causally related to treatment / all	2 / 10	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0
Hypomagnesaemia		
subjects affected / exposed	2 / 4229 (0.05%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hyponatraemia		
subjects affected / exposed	12 / 4229 (0.28%)	6 / 4203 (0.14%)
occurrences causally related to treatment / all	2 / 13	1 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Hypovolaemia		
subjects affected / exposed	2 / 4229 (0.05%)	3 / 4203 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoproteinaemia		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Iron deficiency		
subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Insulin resistance		

subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Metabolic acidosis</b>		
subjects affected / exposed	3 / 4229 (0.07%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Iron overload</b>		
subjects affected / exposed	1 / 4229 (0.02%)	0 / 4203 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Malnutrition</b>		
subjects affected / exposed	1 / 4229 (0.02%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Mineral deficiency</b>		
subjects affected / exposed	0 / 4229 (0.00%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Metabolic disorder</b>		
subjects affected / exposed	1 / 4229 (0.02%)	1 / 4203 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Type 2 diabetes mellitus</b>		
subjects affected / exposed	7 / 4229 (0.17%)	2 / 4203 (0.05%)
occurrences causally related to treatment / all	0 / 7	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0

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

<b>Non-serious adverse events</b>	Enalapril	LCZ696	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1805 / 4229 (42.68%)	1716 / 4203 (40.83%)	
Vascular disorders			
Hypotension			
subjects affected / exposed	454 / 4229 (10.74%)	700 / 4203 (16.65%)	
occurrences (all)	557	890	
Cardiac disorders			
Cardiac failure			
subjects affected / exposed	274 / 4229 (6.48%)	214 / 4203 (5.09%)	
occurrences (all)	359	248	
Nervous system disorders			
Dizziness			
subjects affected / exposed	202 / 4229 (4.78%)	259 / 4203 (6.16%)	
occurrences (all)	232	320	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	528 / 4229 (12.49%)	367 / 4203 (8.73%)	
occurrences (all)	695	488	
Dyspnoea			
subjects affected / exposed	263 / 4229 (6.22%)	173 / 4203 (4.12%)	
occurrences (all)	310	221	
Renal and urinary disorders			
Renal impairment			
subjects affected / exposed	449 / 4229 (10.62%)	393 / 4203 (9.35%)	
occurrences (all)	570	489	
Metabolism and nutrition disorders			
Hyperkalaemia			
subjects affected / exposed	569 / 4229 (13.45%)	477 / 4203 (11.35%)	
occurrences (all)	837	686	

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
15 December 2010	<p>Amendment 1: The purpose is to modify the left ventricular ejection fraction (LVEF) inclusion criterion to <math>\leq 35\%</math> from <math>\leq 40\%</math>. This modification is essential to ensure an adequate event rate in the study population where use of evidence-based, disease-modifying agents is increasing. Modify the estimated glomerular filtration rate (eGFR) reduction criterion for continuation in the run-in period to <math>\leq 35\%</math> from <math>\leq 25\%</math>. This modification will provide the investigator with greater discretion in deciding whether to continue the patient in the study, now that greater safety experience with LCZ696 has been gained from ongoing clinical trials in heart failure. Consider use of aldosterone antagonists for all patients with heart failure (HF) rather than advanced HF only. Incorporate input from health authorities on the unblinding of suspected unexpected serious adverse events (SUSARs) to avoid the unblinding of SAEs which are also efficacy endpoints in the trial and, hence, the potential unblinding of investigators and patients to randomized treatment allocation). Exclusion of patient with bilateral renal artery stenosis since renin-angiotensin antagonists, such as the study meds, can cause significant renal dysfunction in patients with this condition. Insertion of cautionary statements about the concomitant administration of PDE-5 inhibitors, neseritide, and intravenous nitrates since the interaction between these blood pressure lowering agents and LCZ696 has not been studied. Inclusion of fasting plasma glucose measurement at Visits 1, 5, and annually thereafter to assess the prevalence of diabetes mellitus at screening and to more routinely check for its incidence. Additional BNP and NT-proBNP measurements at Visit 3 in the biomarker substudy patients to assess the levels of these biomarkers before start of LCZ696 therapy. Addition of pharmacogenetic substudy. Addition of one more futility analysis; added a more conservative approach for stopping the study early for efficacy.</p>
14 June 2011	<p>Amendment 2: The purpose of the current amendment is to Add more details on the pharmacogenetic substudy assessments, quality control, and data analysis. Clarify that study bioanalytical monitor and the bioanalyst at the bioanalytical site will be unblinded to facilitate timely pharmacokinetic analysis of LCZ696 samples. Change abbreviated chemistry panel at Visit 3 (end of enalapril run-in /before LCZ696 run-in) and at Visits 8 and 9 (2 and 4 months after start of randomized, double-blind treatment period, respectively) to complete serum chemistry assessments. This will be implemented to assess the safety profile of enalapril during the run-in period before patients start the LCZ696 run-in period and to more comprehensively assess the safety profile shortly (2 and 4 months) after initiation of double-blind treatment. Add more instructions on appropriate follow-up of adverse events and clinically relevant laboratory abnormalities. Clarify long-term follow-up procedures during the double-blind period in this outcome trial to reduce loss to follow-up. Add guidance on frequency of re-screening.</p>
07 March 2013	<p>Amendment 3: The purpose of the current amendment is to elevate a pre-specified exploratory objective, i.e., comparing the effects of LCZ696 and enalapril on delaying time to new onset atrial fibrillation, to a secondary objective. The rationale for this change is based on the Recent published data from Study CLCZ696B2214, also known as PARAMOUNT, which demonstrated that LCZ696 treatment in heart failure with preserved ejection fraction results in significant reductions in left atrial volume and left atrial dimension. In addition, safety analysis of this study showed that fewer patients treated with LCZ696 experienced atrial fibrillation as an adverse event than those treated with the comparator (data on file). Therefore, it is hypothesized that LCZ696 may reduce new onset atrial fibrillation to a greater extent than enalapril in patients with heart failure.</p>

26 March 2014

Amendment 4: The purpose of the current amendment is to include procedures requested by the Czech Republic health authority (SUKL). Czech Republic patients will be required to undergo an evaluation of cognitive function by a specialist (e.g., a neurologist or a psychiatrist) every six months for the remaining duration of the study and for one year after dis-continuation of study medication.

Notes:

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### **Interruptions (globally)**

Were there any global interruptions to the trial? No

### **Limitations and caveats**

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

DMC conducted the final interim analysis 28-Mar-14 and recommended early termination due to compelling efficacy of LCZ696 in HF patients and reduced EF. The PARADIGM-HF Executive Committee accepted the recommendation after consultation with Novartis.

Notes: