



Clinical trial results:

Effect of ivabradine in patients with stable coronary artery disease without clinical heart failure. A randomised double-blind placebo-controlled international multicentre study.

Study assessINg the morbi-mortality beNefits of the If inhibitor ivabradine in patients with coronary arterY disease (SIGNIFY).

Due to a system error, the data reported in v1 is not correct and has been removed from public view.

Summary

EudraCT number	2009-011360-10
Trial protocol	ES PT GB NL FI LV HU CZ SK IE BE FR LT DE AT SE IT GR EE SI
Global end of trial date	24 January 2014

Results information

Result version number	v2 (current)
This version publication date	22 July 2016
First version publication date	31 July 2015

Version creation reason	<ul style="list-style-type: none">• Correction of full data set Data correction due to a system error in EudraCT – Results
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Trial information

Trial identification

Sponsor protocol code	CL3-16257-083
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Additional study identifiers

ISRCTN number	ISRCTN61576291
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Institut de Recherches Internationales Servier
Sponsor organisation address	50 rue Carnot, Suresnes Cedex, France, 92284
Public contact	Therapeutic Innovation Pole, Institut de Recherches Internationales Servier 50 rue Carnot 92284 Suresnes Cedex, +33 155724366, clinicaltrials@servier.com
Scientific contact	Therapeutic Innovation Pole, Institut de Recherches Internationales Servier 50 rue Carnot 92284 Suresnes Cedex, +33 155724366, clinicaltrials@servier.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	24 January 2014
Is this the analysis of the primary completion data?	Yes
Primary completion date	24 January 2014
Global end of trial reached?	Yes
Global end of trial date	24 January 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To demonstrate the superiority of ivabradine over placebo in the reduction of CV mortality or non-fatal myocardial infarction.

Protection of trial subjects:

Reason to discontinue the study treatment: study drug not tolerated, no longer appropriate or considered as contra-indicated.

The measurement of drug concentrations in blood was planned in the case of suspected overdose.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	25 September 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	Korea, Republic of: 446
Country: Number of subjects enrolled	Kazakhstan: 141
Country: Number of subjects enrolled	Latvia: 440
Country: Number of subjects enrolled	Lithuania: 302
Country: Number of subjects enrolled	Macedonia, the former Yugoslav Republic of: 224
Country: Number of subjects enrolled	Malaysia: 74
Country: Number of subjects enrolled	Mexico: 559
Country: Number of subjects enrolled	Netherlands: 555
Country: Number of subjects enrolled	Norway: 56
Country: Number of subjects enrolled	Philippines: 30
Country: Number of subjects enrolled	Poland: 1157

Country: Number of subjects enrolled	Portugal: 27
Country: Number of subjects enrolled	Romania: 892
Country: Number of subjects enrolled	Russian Federation: 2119
Country: Number of subjects enrolled	Serbia: 210
Country: Number of subjects enrolled	Singapore: 21
Country: Number of subjects enrolled	Slovenia: 68
Country: Number of subjects enrolled	South Africa: 374
Country: Number of subjects enrolled	Spain: 235
Country: Number of subjects enrolled	Sweden: 57
Country: Number of subjects enrolled	Switzerland: 50
Country: Number of subjects enrolled	Taiwan: 198
Country: Number of subjects enrolled	Thailand: 96
Country: Number of subjects enrolled	Turkey: 96
Country: Number of subjects enrolled	Ukraine: 1894
Country: Number of subjects enrolled	United Kingdom: 118
Country: Number of subjects enrolled	Uruguay: 29
Country: Number of subjects enrolled	Vietnam: 171
Country: Number of subjects enrolled	Argentina: 954
Country: Number of subjects enrolled	Armenia: 239
Country: Number of subjects enrolled	Australia: 116
Country: Number of subjects enrolled	Austria: 19
Country: Number of subjects enrolled	Belgium: 52
Country: Number of subjects enrolled	Brazil: 853
Country: Number of subjects enrolled	Bulgaria: 1121
Country: Number of subjects enrolled	Canada: 254
Country: Number of subjects enrolled	China: 975
Country: Number of subjects enrolled	Croatia: 197
Country: Number of subjects enrolled	Czech Republic: 539
Country: Number of subjects enrolled	Denmark: 76
Country: Number of subjects enrolled	Estonia: 387
Country: Number of subjects enrolled	Finland: 8
Country: Number of subjects enrolled	France: 99
Country: Number of subjects enrolled	Georgia: 102
Country: Number of subjects enrolled	Germany: 309
Country: Number of subjects enrolled	Greece: 77
Country: Number of subjects enrolled	Hungary: 981
Country: Number of subjects enrolled	Slovakia: 379
Country: Number of subjects enrolled	India: 295
Country: Number of subjects enrolled	Ireland: 47
Country: Number of subjects enrolled	Italy: 384
Worldwide total number of subjects	19102
EEA total number of subjects	8582

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	0

months)	
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	10205
From 65 to 84 years	8789
85 years and over	108

Subject disposition

Recruitment

Recruitment details:

A total of 1181 centres in 51 countries screened at least one patient and 1139 centres included at least one patient.

Pre-assignment

Screening details:

A total of 23 164 patients were screened, 21 862 were selected and 19 107 were included. The Randomised Set comprised 19 102 patients: 9550 patients in the ivabradine group and 9552 in the placebo group. Of the 19 102 patients in the Randomised Set, 17 724 completed the study: 8830 patients in the ivabradine group and 8894 in the placebo group.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Ivabradine

Arm description:

Patients taking Ivabradine

Arm type	Study drug
Investigational medicinal product name	Ivabradine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

5 mg, 7.5 mg or 10 mg tablets to be taken orally twice daily at 12-hours intervals, in the morning and in the evening during meals.

Arm title	Placebo
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Arm description:

Patients taking placebo

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

5 mg, 7.5 mg or 10 mg matching tablets to be taken orally twice daily at 12-hours intervals, in the morning and in the evening during meals.

Number of subjects in period 1	Ivabradine	Placebo
Started	9550	9552
Completed	8830	8894
Not completed	720	658
Adverse event, serious fatal	485	458
Consent withdrawn by subject	231	199
Physician decision	1	-
Lost to follow-up	3	1

Baseline characteristics

Reporting groups

Reporting group title	Ivabradine
Reporting group description: Patients taking Ivabradine	
Reporting group title	Placebo
Reporting group description: Patients taking placebo	

Reporting group values	Ivabradine	Placebo	Total
Number of subjects	9550	9552	19102
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)	5109	5096	10205
From 65-84 years	4387	4402	8789
85 years and over	54	54	108
Age continuous			
Units: years			
arithmetic mean	65	65	
standard deviation	± 7.2	± 7.3	-
Gender categorical			
Units: Subjects			
Female	2601	2662	5263
Male	6949	6890	13839

Subject analysis sets

Subject analysis set title	Randomised set
Subject analysis set type	Intention-to-treat
Subject analysis set description: All included patients with a randomisation number allocated by the IRS.	
Subject analysis set title	Safety set
Subject analysis set type	Safety analysis
Subject analysis set description: All patients having received at least one dose of study drug.	
Subject analysis set title	Randomised set angina
Subject analysis set type	Intention-to-treat
Subject analysis set description: All symptomatic angina patients of the RS having a CCS class ≥ II at baseline (defined as CCS class ≥ II at selection and inclusion).	
Subject analysis set title	Safety set angina

Subject analysis set type	Safety analysis
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Subject analysis set description:

All symptomatic angina patients of the SS having a CCS class \geq II at baseline (defined as CCS class \geq II at selection and inclusion).

Reporting group values	Randomised set	Safety set	Randomised set angina
Number of subjects	19102	19083	1204
Age categorical Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	0		
Newborns (0-27 days)	0		
Infants and toddlers (28 days-23 months)	0		
Children (2-11 years)	0		
Adolescents (12-17 years)	0		
Adults (18-64 years)	5109		
From 65-84 years	4387		
85 years and over	54		
Age continuous Units: years			
arithmetic mean	65		
standard deviation	± 7.2	\pm	\pm
Gender categorical Units: Subjects			
Female	5263		
Male	13839		

Reporting group values	Safety set angina		
Number of subjects	1203		
Age categorical Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)			
From 65-84 years			
85 years and over			
Age continuous Units: years			
arithmetic mean			
standard deviation	\pm		
Gender categorical Units: Subjects			
Female			
Male			

End points

End points reporting groups

Reporting group title	Ivabradine
Reporting group description:	
Patients taking Ivabradine	
Reporting group title	Placebo
Reporting group description:	
Patients taking placebo	
Subject analysis set title	Randomised set
Subject analysis set type	Intention-to-treat
Subject analysis set description:	
All included patients with a randomisation number allocated by the IRS.	
Subject analysis set title	Safety set
Subject analysis set type	Safety analysis
Subject analysis set description:	
All patients having received at least one dose of study drug.	
Subject analysis set title	Randomised set angina
Subject analysis set type	Intention-to-treat
Subject analysis set description:	
All symptomatic angina patients of the RS having a CCS class \geq II at baseline (defined as CCS class \geq II at selection and inclusion).	
Subject analysis set title	Safety set angina
Subject analysis set type	Safety analysis
Subject analysis set description:	
All symptomatic angina patients of the SS having a CCS class \geq II at baseline (defined as CCS class \geq II at selection and inclusion).	

Primary: Primary composite endpoint

End point title	Primary composite endpoint
End point description:	
First event among cardiovascular death or non-fatal MI	
End point type	Primary
End point timeframe:	
All criteria are expressed as the time to first event, defined as the duration between the date of randomisation and the date of first occurrence of this event.	

End point values	Ivabradine	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9550	9552		
Units: number of events	654	611		

Statistical analyses

Statistical analysis title	Superiority of Ivabradine versus Placebo
Comparison groups	Ivabradine v Placebo
Number of subjects included in analysis	19102
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1969
Method	Regression, Cox
Parameter estimate	Cox proportional hazard
Point estimate	1.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.96
upper limit	1.2
Variability estimate	Standard error of the mean
Dispersion value	0.06

Adverse events

Adverse events information

Timeframe for reporting adverse events:

On treatment

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	16.0
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Reporting groups

Reporting group title	Ivabradine
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Reporting group description: -

Reporting group title	Placebo
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Reporting group description: -

Serious adverse events	Ivabradine	Placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	3379 / 9539 (35.42%)	3263 / 9544 (34.19%)	
number of deaths (all causes)	363	356	
number of deaths resulting from adverse events	1	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute leukaemia			
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Acute myeloid leukaemia			
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adenocarcinoma gastric			
subjects affected / exposed	6 / 9539 (0.06%)	4 / 9544 (0.04%)	
occurrences causally related to treatment / all	0 / 6	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 2	
Adenocarcinoma of colon			

subjects affected / exposed	8 / 9539 (0.08%)	7 / 9544 (0.07%)
occurrences causally related to treatment / all	0 / 8	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Adenocarcinoma pancreas		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Adenolymphoma		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Adrenal adenoma		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Adenosquamous cell lung cancer		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Anal squamous cell carcinoma		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Angiofibroma		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Astrocytoma, low grade		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
B precursor type acute leukaemia		

subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
B-cell lymphoma		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Basal cell carcinoma		
subjects affected / exposed	24 / 9539 (0.25%)	21 / 9544 (0.22%)
occurrences causally related to treatment / all	0 / 25	0 / 23
deaths causally related to treatment / all	0 / 0	0 / 0
Basosquamous carcinoma		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Basosquamous carcinoma of skin		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Benign breast neoplasm		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Benign neoplasm of prostate		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Benign neoplasm of thyroid gland		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Benign pleural neoplasm		

subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Benign renal neoplasm		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bile duct cancer		
subjects affected / exposed	2 / 9539 (0.02%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder cancer		
subjects affected / exposed	6 / 9539 (0.06%)	9 / 9544 (0.09%)
occurrences causally related to treatment / all	0 / 6	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder cancer recurrent		
subjects affected / exposed	0 / 9539 (0.00%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder cancer stage I, with cancer in situ		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder cancer stage II		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder neoplasm		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder papilloma		

subjects affected / exposed	1 / 9539 (0.01%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder transitional cell carcinoma		
subjects affected / exposed	5 / 9539 (0.05%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder transitional cell carcinoma recurrent		
subjects affected / exposed	2 / 9539 (0.02%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder transitional cell carcinoma stage II		
subjects affected / exposed	1 / 9539 (0.01%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder transitional cell carcinoma stage III		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bowen's disease		
subjects affected / exposed	3 / 9539 (0.03%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Brain cancer metastatic		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (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 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Brain neoplasm malignant		

subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
Brain stem glioma		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Breast cancer		
subjects affected / exposed	0 / 9539 (0.00%)	5 / 9544 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Breast cancer metastatic		
subjects affected / exposed	2 / 9539 (0.02%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 1
Breast cancer recurrent		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Breast cancer stage I		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Breast cancer stage II		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchial carcinoma		
subjects affected / exposed	5 / 9539 (0.05%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchioloalveolar carcinoma		

subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cancer pain		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Carcinoid tumour of the stomach		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Carotid body tumour		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Castleman's disease		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral hygroma		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cervix carcinoma		
subjects affected / exposed	0 / 9539 (0.00%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Cervix carcinoma stage III		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cholangiocarcinoma		

subjects affected / exposed	0 / 9539 (0.00%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Cholesteatoma		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic lymphocytic leukaemia		
subjects affected / exposed	3 / 9539 (0.03%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic lymphocytic leukaemia stage 2		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
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 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Clear cell sarcoma of soft tissue		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Colon adenoma		
subjects affected / exposed	4 / 9539 (0.04%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Colon cancer		
subjects affected / exposed	6 / 9539 (0.06%)	5 / 9544 (0.05%)
occurrences causally related to treatment / all	0 / 6	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Colon cancer metastatic		

subjects affected / exposed	6 / 9539 (0.06%)	7 / 9544 (0.07%)
occurrences causally related to treatment / all	0 / 6	0 / 7
deaths causally related to treatment / all	0 / 3	0 / 1
Colon cancer stage 0		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Colorectal cancer		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Colorectal cancer metastatic		
subjects affected / exposed	2 / 9539 (0.02%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diffuse large B-cell lymphoma		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
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 stage III		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diffuse large B-cell lymphoma stage IV		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ear neoplasm malignant		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Endometrial adenocarcinoma		

subjects affected / exposed	2 / 9539 (0.02%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ependymoma		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Extranodal marginal zone B-cell lymphoma (MALT type)		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gallbladder cancer		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gallbladder neoplasm		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric adenoma		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric cancer		
subjects affected / exposed	3 / 9539 (0.03%)	8 / 9544 (0.08%)
occurrences causally related to treatment / all	0 / 3	0 / 8
deaths causally related to treatment / all	0 / 1	0 / 2
Gastric cancer stage IV		
subjects affected / exposed	3 / 9539 (0.03%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal carcinoma		

subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal stromal tumour		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal tract adenoma		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrooesophageal cancer		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
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 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Haemangioma of bone		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic cancer		
subjects affected / exposed	3 / 9539 (0.03%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 3	0 / 0
Hepatic cancer metastatic		
subjects affected / exposed	2 / 9539 (0.02%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 2	0 / 2
Hepatocellular carcinoma		

subjects affected / exposed	2 / 9539 (0.02%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hodgkin's disease		
subjects affected / exposed	2 / 9539 (0.02%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal adenocarcinoma		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Invasive ductal breast carcinoma		
subjects affected / exposed	4 / 9539 (0.04%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Large cell lung cancer		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Large cell lung cancer metastatic		
subjects affected / exposed	2 / 9539 (0.02%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0
Large cell lung cancer stage II		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (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 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Laryngeal cancer		

subjects affected / exposed	2 / 9539 (0.02%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Laryngeal cancer metastatic		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Laryngeal cancer recurrent		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Laryngeal squamous cell carcinoma		
subjects affected / exposed	1 / 9539 (0.01%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 1
Lentigo maligna		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lip and/or oral cavity cancer		
subjects affected / exposed	2 / 9539 (0.02%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 2	0 / 0
Lip and/or oral cavity cancer stage IV		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lipoma		
subjects affected / exposed	2 / 9539 (0.02%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lung adenocarcinoma		

subjects affected / exposed	4 / 9539 (0.04%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Lung adenocarcinoma metastatic		
subjects affected / exposed	5 / 9539 (0.05%)	8 / 9544 (0.08%)
occurrences causally related to treatment / all	0 / 5	0 / 9
deaths causally related to treatment / all	0 / 2	0 / 6
Lung adenocarcinoma stage IV		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lung cancer metastatic		
subjects affected / exposed	5 / 9539 (0.05%)	10 / 9544 (0.10%)
occurrences causally related to treatment / all	0 / 5	0 / 10
deaths causally related to treatment / all	0 / 2	0 / 6
Lung carcinoma cell type unspecified stage II		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Lung carcinoma cell type unspecified stage IV		
subjects affected / exposed	3 / 9539 (0.03%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Lung neoplasm		
subjects affected / exposed	1 / 9539 (0.01%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 2
Lung neoplasm malignant		
subjects affected / exposed	7 / 9539 (0.07%)	12 / 9544 (0.13%)
occurrences causally related to treatment / all	0 / 7	0 / 12
deaths causally related to treatment / all	0 / 3	0 / 5
Lung squamous cell carcinoma metastatic		

subjects affected / exposed	0 / 9539 (0.00%)	3 / 9544 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 2	
Lung squamous cell carcinoma stage III			
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphangiosis carcinomatosa			
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Malignant ascites			
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant glioma			
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Malignant melanoma			
subjects affected / exposed	2 / 9539 (0.02%)	2 / 9544 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant neoplasm of ampulla of Vater			
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant neoplasm of choroid			
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant neoplasm of eyelid			

subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Malignant oligodendroglioma		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Malignant pleural effusion		
subjects affected / exposed	3 / 9539 (0.03%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Meningioma		
subjects affected / exposed	1 / 9539 (0.01%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Mesothelioma		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Metastases to abdominal cavity		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Metastases to adrenals		
subjects affected / exposed	2 / 9539 (0.02%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Metastases to bone		
subjects affected / exposed	3 / 9539 (0.03%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 2	0 / 0
Metastases to bone marrow		

subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Metastases to central nervous system		
subjects affected / exposed	3 / 9539 (0.03%)	4 / 9544 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 2	0 / 0
Metastases to eye		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Metastases to liver		
subjects affected / exposed	3 / 9539 (0.03%)	4 / 9544 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 1
Metastases to lung		
subjects affected / exposed	2 / 9539 (0.02%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Metastases to lymph nodes		
subjects affected / exposed	0 / 9539 (0.00%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Metastases to peritoneum		
subjects affected / exposed	0 / 9539 (0.00%)	4 / 9544 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 1
Metastases to the mediastinum		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Metastases to spine		

subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Metastatic bronchial carcinoma		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
Metastatic carcinoma of the bladder		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Metastatic gastric cancer		
subjects affected / exposed	3 / 9539 (0.03%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 2	0 / 2
Metastatic malignant melanoma		
subjects affected / exposed	0 / 9539 (0.00%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 1
Metastatic neoplasm		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Metastatic renal cell carcinoma		
subjects affected / exposed	2 / 9539 (0.02%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0
Metastatic pain		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Metastatic squamous cell carcinoma		

subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Metastatic uterine cancer		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
Myelodysplastic syndrome		
subjects affected / exposed	2 / 9539 (0.02%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Myelofibrosis		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Myeloproliferative disorder		
subjects affected / exposed	4 / 9539 (0.04%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nasopharyngeal cancer		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Neoplasm		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neoplasm skin		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neuroendocrine carcinoma metastatic		

subjects affected / exposed	0 / 9539 (0.00%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Neuroendocrine tumour		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Neuroma		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Nodular melanoma		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Non-Hodgkin's lymphoma		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Non-small cell lung cancer		
subjects affected / exposed	3 / 9539 (0.03%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Non-small cell lung cancer metastatic		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Non-small cell lung cancer stage IIIA		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal adenocarcinoma		

subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal adenocarcinoma metastatic		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal carcinoma		
subjects affected / exposed	2 / 9539 (0.02%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Oesophageal squamous cell carcinoma		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Oropharyngeal cancer		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ovarian adenoma		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ovarian cancer		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Ovarian cancer metastatic		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ovarian epithelial cancer metastatic		

subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ovarian germ cell teratoma benign		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatic carcinoma		
subjects affected / exposed	2 / 9539 (0.02%)	4 / 9544 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 1
Pancreatic carcinoma metastatic		
subjects affected / exposed	7 / 9539 (0.07%)	8 / 9544 (0.08%)
occurrences causally related to treatment / all	0 / 7	0 / 8
deaths causally related to treatment / all	0 / 4	0 / 3
Pancreatic neoplasm		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Papillary tumour of renal pelvis		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Parathyroid tumour benign		
subjects affected / exposed	1 / 9539 (0.01%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Penis carcinoma stage II		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Pharyngeal cancer recurrent		

subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Pineal parenchymal neoplasm malignant		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Pituitary tumour benign		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pituitary tumour recurrent		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Plasma cell leukaemia		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Plasma cell myeloma		
subjects affected / exposed	2 / 9539 (0.02%)	4 / 9544 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 2
Pleural mesothelioma		
subjects affected / exposed	2 / 9539 (0.02%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pleural neoplasm		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Polycythaemia vera		

subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
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	38 / 9539 (0.40%)	18 / 9544 (0.19%)
occurrences causally related to treatment / all	0 / 38	0 / 18
deaths causally related to treatment / all	0 / 0	0 / 0
Prostate cancer metastatic		
subjects affected / exposed	4 / 9539 (0.04%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Prostate cancer recurrent		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Prostate cancer stage I		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Prostate cancer stage II		
subjects affected / exposed	0 / 9539 (0.00%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Prostate cancer stage III		
subjects affected / exposed	1 / 9539 (0.01%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Prostate cancer stage IV		
subjects affected / exposed	1 / 9539 (0.01%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Prostatic adenoma		

subjects affected / exposed	4 / 9539 (0.04%)	5 / 9544 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal adenocarcinoma		
subjects affected / exposed	1 / 9539 (0.01%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal cancer		
subjects affected / exposed	5 / 9539 (0.05%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0
Rectal cancer metastatic		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Rectal cancer recurrent		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal cancer stage 0		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal cancer stage IV		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Rectosigmoid cancer		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal neoplasm		

subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal cancer		
subjects affected / exposed	6 / 9539 (0.06%)	5 / 9544 (0.05%)
occurrences causally related to treatment / all	0 / 6	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 0
Renal cancer metastatic		
subjects affected / exposed	4 / 9539 (0.04%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Renal cancer stage I		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renal oncocytoma		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renal cell carcinoma		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Rhabdomyosarcoma		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Salivary gland adenoma		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Salivary gland cancer		

subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Skin cancer metastatic		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Skin cancer		
subjects affected / exposed	4 / 9539 (0.04%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Small cell lung cancer		
subjects affected / exposed	1 / 9539 (0.01%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
Small cell lung cancer metastatic		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Small intestine carcinoma		
subjects affected / exposed	2 / 9539 (0.02%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal meningioma benign		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Squamous cell carcinoma		
subjects affected / exposed	3 / 9539 (0.03%)	4 / 9544 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 0
Squamous cell carcinoma of head and neck		

subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous cell carcinoma of lung			
subjects affected / exposed	4 / 9539 (0.04%)	5 / 9544 (0.05%)	
occurrences causally related to treatment / all	0 / 4	0 / 5	
deaths causally related to treatment / all	0 / 2	0 / 2	
Squamous cell carcinoma of pharynx			
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous cell carcinoma of skin			
subjects affected / exposed	2 / 9539 (0.02%)	2 / 9544 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous cell carcinoma of the cervix			
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Squamous cell carcinoma of the hypopharynx			
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous cell carcinoma of the oral cavity			
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Testicular cancer metastatic			
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Throat cancer			

subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroid cancer metastatic			
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroid neoplasm			
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tongue neoplasm malignant stage unspecified			
subjects affected / exposed	2 / 9539 (0.02%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 2	0 / 0	
Tonsil cancer			
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Transitional cell carcinoma			
subjects affected / exposed	1 / 9539 (0.01%)	3 / 9544 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urethral cancer metastatic			
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine leiomyoma			
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vulval cancer			

subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Aortic aneurysm			
subjects affected / exposed	4 / 9539 (0.04%)	7 / 9544 (0.07%)	
occurrences causally related to treatment / all	0 / 4	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic aneurysm rupture			
subjects affected / exposed	2 / 9539 (0.02%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 2	0 / 0	
Aortic arteriosclerosis			
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic dilatation			
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic dissection			
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic occlusion			
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic thrombosis			
subjects affected / exposed	5 / 9539 (0.05%)	2 / 9544 (0.02%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arterial rupture			

subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Arterial stenosis		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Arteriosclerosis		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Blood pressure fluctuation		
subjects affected / exposed	2 / 9539 (0.02%)	0 / 9544 (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	7 / 9539 (0.07%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	1 / 8	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Circulatory collapse		
subjects affected / exposed	2 / 9539 (0.02%)	7 / 9544 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Deep vein thrombosis		
subjects affected / exposed	19 / 9539 (0.20%)	17 / 9544 (0.18%)
occurrences causally related to treatment / all	0 / 19	1 / 17
deaths causally related to treatment / all	0 / 0	0 / 1
Diabetic macroangiopathy		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic microangiopathy		

subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic vascular disorder		
subjects affected / exposed	3 / 9539 (0.03%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Embolism		
subjects affected / exposed	1 / 9539 (0.01%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Essential hypertension		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
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	5 / 9539 (0.05%)	7 / 9544 (0.07%)
occurrences causally related to treatment / all	0 / 6	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Femoral artery aneurysm		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Femoral artery dissection		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Femoral artery embolism		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Femoral artery occlusion		

subjects affected / exposed	10 / 9539 (0.10%)	14 / 9544 (0.15%)
occurrences causally related to treatment / all	0 / 11	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhage		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertension		
subjects affected / exposed	204 / 9539 (2.14%)	144 / 9544 (1.51%)
occurrences causally related to treatment / all	2 / 220	0 / 152
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertensive crisis		
subjects affected / exposed	104 / 9539 (1.09%)	105 / 9544 (1.10%)
occurrences causally related to treatment / all	1 / 117	0 / 119
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertensive emergency		
subjects affected / exposed	13 / 9539 (0.14%)	8 / 9544 (0.08%)
occurrences causally related to treatment / all	1 / 15	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Hypotension		
subjects affected / exposed	25 / 9539 (0.26%)	36 / 9544 (0.38%)
occurrences causally related to treatment / all	5 / 26	0 / 37
deaths causally related to treatment / all	0 / 0	0 / 0
Hypovolaemic shock		
subjects affected / exposed	1 / 9539 (0.01%)	4 / 9544 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 1
Iliac artery occlusion		
subjects affected / exposed	1 / 9539 (0.01%)	4 / 9544 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Iliac artery rupture		

subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (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	5 / 9539 (0.05%)	8 / 9544 (0.08%)
occurrences causally related to treatment / all	0 / 5	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Jugular vein thrombosis		
subjects affected / exposed	2 / 9539 (0.02%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Labile blood pressure		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Labile hypertension		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Leriche syndrome		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphoedema		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphostasis		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Malignant hypertension		

subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (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	12 / 9539 (0.13%)	6 / 9544 (0.06%)
occurrences causally related to treatment / all	2 / 12	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Pallor		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral arterial occlusive disease		
subjects affected / exposed	52 / 9539 (0.55%)	67 / 9544 (0.70%)
occurrences causally related to treatment / all	0 / 58	0 / 70
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery aneurysm		
subjects affected / exposed	3 / 9539 (0.03%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery dissection		
subjects affected / exposed	0 / 9539 (0.00%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery stenosis		
subjects affected / exposed	13 / 9539 (0.14%)	12 / 9544 (0.13%)
occurrences causally related to treatment / all	0 / 16	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery thrombosis		
subjects affected / exposed	6 / 9539 (0.06%)	6 / 9544 (0.06%)
occurrences causally related to treatment / all	0 / 6	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral embolism		

subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral ischaemia		
subjects affected / exposed	5 / 9539 (0.05%)	8 / 9544 (0.08%)
occurrences causally related to treatment / all	0 / 5	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 1
Peripheral vascular disorder		
subjects affected / exposed	1 / 9539 (0.01%)	5 / 9544 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Phlebitis		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Phlebitis superficial		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Shock haemorrhagic		
subjects affected / exposed	3 / 9539 (0.03%)	5 / 9544 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 1	0 / 1
Subclavian artery occlusion		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Subclavian artery stenosis		
subjects affected / exposed	2 / 9539 (0.02%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Subclavian steal syndrome		

subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Subgaleal haematoma		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Systolic hypertension		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Thrombophlebitis		
subjects affected / exposed	5 / 9539 (0.05%)	6 / 9544 (0.06%)
occurrences causally related to treatment / all	0 / 5	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Thrombophlebitis superficial		
subjects affected / exposed	2 / 9539 (0.02%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Thrombosis		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Varicose ulceration		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Varicose vein		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vasculitis		

subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vasculitis necrotising			
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vena cava thrombosis			
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Venous insufficiency			
subjects affected / exposed	3 / 9539 (0.03%)	2 / 9544 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Venous thrombosis			
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Venous thrombosis limb			
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Withdrawal hypertension			
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
Abdominal hernia repair			
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol detoxification			

subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic aneurysm repair		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic bypass		
subjects affected / exposed	2 / 9539 (0.02%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic valve repair		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic valve replacement		
subjects affected / exposed	0 / 9539 (0.00%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Arterial bypass operation		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Arterial stent insertion		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Arteriovenous fistula operation		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder neoplasm surgery		

subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Blepharoplasty		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bunion operation		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac ablation		
subjects affected / exposed	0 / 9539 (0.00%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac aneurysm repair		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac rehabilitation therapy		
subjects affected / exposed	23 / 9539 (0.24%)	19 / 9544 (0.20%)
occurrences causally related to treatment / all	0 / 30	0 / 27
deaths causally related to treatment / all	0 / 0	0 / 0
Carotid angioplasty		
subjects affected / exposed	2 / 9539 (0.02%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Carotid artery bypass		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Carotid artery stent insertion		

subjects affected / exposed	2 / 9539 (0.02%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Carotid endarterectomy		
subjects affected / exposed	2 / 9539 (0.02%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Cataract operation		
subjects affected / exposed	9 / 9539 (0.09%)	9 / 9544 (0.09%)
occurrences causally related to treatment / all	0 / 9	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Chemotherapy		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cholecystectomy		
subjects affected / exposed	6 / 9539 (0.06%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 6	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cholesteatoma removal		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Circumcision		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary angioplasty		
subjects affected / exposed	1 / 9539 (0.01%)	5 / 9544 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary arterial stent insertion		

subjects affected / exposed	5 / 9539 (0.05%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery bypass		
subjects affected / exposed	10 / 9539 (0.10%)	18 / 9544 (0.19%)
occurrences causally related to treatment / all	0 / 10	0 / 18
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary revascularisation		
subjects affected / exposed	8 / 9539 (0.08%)	5 / 9544 (0.05%)
occurrences causally related to treatment / all	0 / 8	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetes mellitus management		
subjects affected / exposed	4 / 9539 (0.04%)	8 / 9544 (0.08%)
occurrences causally related to treatment / all	0 / 5	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0
Dupuytren's contracture operation		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Fasciectomy		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Femoral hernia repair		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Finger amputation		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrectomy		

subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric banding		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric bypass		
subjects affected / exposed	0 / 9539 (0.00%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Glaucoma surgery		
subjects affected / exposed	0 / 9539 (0.00%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hip arthroplasty		
subjects affected / exposed	9 / 9539 (0.09%)	9 / 9544 (0.09%)
occurrences causally related to treatment / all	0 / 10	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Hospitalisation		
subjects affected / exposed	8 / 9539 (0.08%)	10 / 9544 (0.10%)
occurrences causally related to treatment / all	0 / 13	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Hydrocele operation		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ileostomy closure		
subjects affected / exposed	0 / 9539 (0.00%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Implantable defibrillator insertion		

subjects affected / exposed	2 / 9539 (0.02%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Incisional hernia repair		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Infusion		
subjects affected / exposed	0 / 9539 (0.00%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Inguinal hernia repair		
subjects affected / exposed	3 / 9539 (0.03%)	9 / 9544 (0.09%)
occurrences causally related to treatment / all	0 / 3	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Internal fixation of fracture		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intraocular lens extraction		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Keratoplasty		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Knee arthroplasty		
subjects affected / exposed	4 / 9539 (0.04%)	12 / 9544 (0.13%)
occurrences causally related to treatment / all	0 / 4	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0
Knee operation		

subjects affected / exposed	1 / 9539 (0.01%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Leg amputation		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lens extraction		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Medical device removal		
subjects affected / exposed	2 / 9539 (0.02%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Liver operation		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Meniscus removal		
subjects affected / exposed	2 / 9539 (0.02%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Metatarsal excision		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Mitral valve repair		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nasal polypectomy		

subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Obesity surgery		
subjects affected / exposed	2 / 9539 (0.02%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Nasal septal operation		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oophorectomy bilateral		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Percutaneous coronary intervention		
subjects affected / exposed	15 / 9539 (0.16%)	16 / 9544 (0.17%)
occurrences causally related to treatment / all	0 / 15	0 / 16
deaths causally related to treatment / all	0 / 1	0 / 0
Peripheral artery angioplasty		
subjects affected / exposed	0 / 9539 (0.00%)	4 / 9544 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery bypass		
subjects affected / exposed	2 / 9539 (0.02%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery stent insertion		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Physiotherapy		

subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Radical hysterectomy		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Radiotherapy		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rehabilitation therapy		
subjects affected / exposed	8 / 9539 (0.08%)	10 / 9544 (0.10%)
occurrences causally related to treatment / all	0 / 12	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0
Removal of internal fixation		
subjects affected / exposed	4 / 9539 (0.04%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal artery ablation		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renal stone removal		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Retinal laser coagulation		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Rotator cuff repair		

subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Shoulder arthroplasty		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sinus operation		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Skin neoplasm excision		
subjects affected / exposed	2 / 9539 (0.02%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal operation		
subjects affected / exposed	0 / 9539 (0.00%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Suture insertion		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Thyroidectomy		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Toe amputation		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Transurethral prostatectomy		

subjects affected / exposed	3 / 9539 (0.03%)	2 / 9544 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Umbilical hernia repair			
subjects affected / exposed	1 / 9539 (0.01%)	2 / 9544 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urethral dilation procedure			
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary calculus removal			
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine polypectomy			
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vaginal prolapse repair			
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Apparent death			
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asthenia			
subjects affected / exposed	3 / 9539 (0.03%)	6 / 9544 (0.06%)	
occurrences causally related to treatment / all	0 / 3	2 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac death			

subjects affected / exposed	0 / 9539 (0.00%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 2
Chest discomfort		
subjects affected / exposed	3 / 9539 (0.03%)	4 / 9544 (0.04%)
occurrences causally related to treatment / all	1 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Chest pain		
subjects affected / exposed	32 / 9539 (0.34%)	36 / 9544 (0.38%)
occurrences causally related to treatment / all	0 / 35	0 / 50
deaths causally related to treatment / all	0 / 0	0 / 0
Chills		
subjects affected / exposed	0 / 9539 (0.00%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Death		
subjects affected / exposed	10 / 9539 (0.10%)	7 / 9544 (0.07%)
occurrences causally related to treatment / all	0 / 10	0 / 7
deaths causally related to treatment / all	0 / 10	0 / 7
Device breakage		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Device dislocation		
subjects affected / exposed	3 / 9539 (0.03%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Device extrusion		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Device failure		

subjects affected / exposed	2 / 9539 (0.02%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Device malfunction		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Device occlusion		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Discomfort		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Drowning		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Drug interaction		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Exercise tolerance decreased		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Face oedema		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Fatigue		

subjects affected / exposed	7 / 9539 (0.07%)	4 / 9544 (0.04%)
occurrences causally related to treatment / all	2 / 7	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Feeling abnormal		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Feeling cold		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Foreign body reaction		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gait disturbance		
subjects affected / exposed	1 / 9539 (0.01%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	1 / 1	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
General physical health deterioration		
subjects affected / exposed	3 / 9539 (0.03%)	2 / 9544 (0.02%)
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	3 / 9539 (0.03%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hernia obstructive		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (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 / 9539 (0.01%)	1 / 9544 (0.01%)
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 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Irritability		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Malaise		
subjects affected / exposed	2 / 9539 (0.02%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Medical device complication		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Multi-organ failure		
subjects affected / exposed	5 / 9539 (0.05%)	8 / 9544 (0.08%)
occurrences causally related to treatment / all	0 / 5	0 / 8
deaths causally related to treatment / all	0 / 3	0 / 3
Non-cardiac chest pain		
subjects affected / exposed	38 / 9539 (0.40%)	29 / 9544 (0.30%)
occurrences causally related to treatment / all	0 / 43	1 / 31
deaths causally related to treatment / all	0 / 0	0 / 0
Oedema peripheral		
subjects affected / exposed	9 / 9539 (0.09%)	6 / 9544 (0.06%)
occurrences causally related to treatment / all	0 / 9	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Pacemaker generated arrhythmia		

subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pain		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Puncture site haemorrhage		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pyrexia		
subjects affected / exposed	5 / 9539 (0.05%)	4 / 9544 (0.04%)
occurrences causally related to treatment / all	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal pain		
subjects affected / exposed	3 / 9539 (0.03%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Stent-graft endoleak		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sudden cardiac death		
subjects affected / exposed	43 / 9539 (0.45%)	46 / 9544 (0.48%)
occurrences causally related to treatment / all	0 / 43	0 / 46
deaths causally related to treatment / all	0 / 43	0 / 46
Sudden death		
subjects affected / exposed	75 / 9539 (0.79%)	74 / 9544 (0.78%)
occurrences causally related to treatment / all	0 / 75	0 / 74
deaths causally related to treatment / all	0 / 75	0 / 74
Systemic inflammatory response syndrome		

subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombosis in device			
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Immune system disorders			
Allergy to arthropod sting			
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Amyloidosis			
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaphylactic reaction			
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaphylactic shock			
subjects affected / exposed	0 / 9539 (0.00%)	2 / 9544 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Drug hypersensitivity			
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Food allergy			
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypersensitivity			

subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Social circumstances			
Activities of daily living impaired			
subjects affected / exposed	11 / 9539 (0.12%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	11 / 11	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol use			
subjects affected / exposed	2 / 9539 (0.02%)	0 / 9544 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immobile			
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Impaired driving ability			
subjects affected / exposed	15 / 9539 (0.16%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	15 / 15	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Acquired hydrocele			
subjects affected / exposed	0 / 9539 (0.00%)	4 / 9544 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acquired phimosis			
subjects affected / exposed	3 / 9539 (0.03%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign prostatic hyperplasia			
subjects affected / exposed	23 / 9539 (0.24%)	28 / 9544 (0.29%)	
occurrences causally related to treatment / all	0 / 23	0 / 28	
deaths causally related to treatment / all	0 / 0	0 / 0	

Breast disorder			
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cystocele			
subjects affected / exposed	2 / 9539 (0.02%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epididymitis			
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Female genital tract fistula			
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Genital prolapse			
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gynaecomastia			
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic adhesions			
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatitis			
subjects affected / exposed	0 / 9539 (0.00%)	3 / 9544 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatomegaly			

subjects affected / exposed	2 / 9539 (0.02%)	2 / 9544 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine prolapse			
subjects affected / exposed	0 / 9539 (0.00%)	2 / 9544 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterovaginal prolapse			
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vaginal haemorrhage			
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Varicocele			
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vulval disorder			
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (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			
Acquired tracheo-oesophageal fistula			
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute pulmonary oedema			
subjects affected / exposed	31 / 9539 (0.32%)	30 / 9544 (0.31%)	
occurrences causally related to treatment / all	0 / 33	0 / 32	
deaths causally related to treatment / all	0 / 4	0 / 4	
Acute respiratory distress syndrome			

subjects affected / exposed	1 / 9539 (0.01%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
Acute respiratory failure		
subjects affected / exposed	13 / 9539 (0.14%)	12 / 9544 (0.13%)
occurrences causally related to treatment / all	1 / 13	0 / 13
deaths causally related to treatment / all	0 / 3	0 / 1
Alveolitis allergic		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Asphyxia		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Asthma		
subjects affected / exposed	21 / 9539 (0.22%)	16 / 9544 (0.17%)
occurrences causally related to treatment / all	0 / 22	0 / 21
deaths causally related to treatment / all	0 / 0	0 / 0
Aspiration		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Asthmatic crisis		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Atelectasis		
subjects affected / exposed	0 / 9539 (0.00%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchiectasis		

subjects affected / exposed	5 / 9539 (0.05%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchitis chronic		
subjects affected / exposed	5 / 9539 (0.05%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	0 / 6	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchopneumopathy		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchospasm		
subjects affected / exposed	5 / 9539 (0.05%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	0 / 5	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Choking		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic obstructive pulmonary disease		
subjects affected / exposed	64 / 9539 (0.67%)	52 / 9544 (0.54%)
occurrences causally related to treatment / all	0 / 84	0 / 62
deaths causally related to treatment / all	0 / 1	0 / 1
Chronic respiratory failure		
subjects affected / exposed	4 / 9539 (0.04%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0
Cough		
subjects affected / exposed	7 / 9539 (0.07%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 7	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cyanosis central		

subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diaphragmatic paralysis		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dyspnoea		
subjects affected / exposed	23 / 9539 (0.24%)	23 / 9544 (0.24%)
occurrences causally related to treatment / all	0 / 25	2 / 26
deaths causally related to treatment / all	0 / 0	0 / 1
Dyspnoea at rest		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dyspnoea exertional		
subjects affected / exposed	1 / 9539 (0.01%)	6 / 9544 (0.06%)
occurrences causally related to treatment / all	1 / 1	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Emphysema		
subjects affected / exposed	1 / 9539 (0.01%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Epistaxis		
subjects affected / exposed	4 / 9539 (0.04%)	6 / 9544 (0.06%)
occurrences causally related to treatment / all	0 / 4	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Granulomatous pneumonitis		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haemoptysis		

subjects affected / exposed	4 / 9539 (0.04%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Haemothorax		
subjects affected / exposed	0 / 9539 (0.00%)	6 / 9544 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Hydropneumothorax		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Hydrothorax		
subjects affected / exposed	6 / 9539 (0.06%)	8 / 9544 (0.08%)
occurrences causally related to treatment / all	0 / 6	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoxia		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Idiopathic pulmonary fibrosis		
subjects affected / exposed	2 / 9539 (0.02%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Interstitial lung disease		
subjects affected / exposed	6 / 9539 (0.06%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	0 / 6	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0
Laryngeal stenosis		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lung consolidation		

subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lung cyst		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lung disorder		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lung infiltration		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nasal polyps		
subjects affected / exposed	2 / 9539 (0.02%)	4 / 9544 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Nasal septum deviation		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Obstructive airways disorder		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Organising pneumonia		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pharyngeal oedema		

subjects affected / exposed	0 / 9539 (0.00%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pickwickian syndrome		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pleural effusion		
subjects affected / exposed	8 / 9539 (0.08%)	7 / 9544 (0.07%)
occurrences causally related to treatment / all	0 / 8	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Pleural fibrosis		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pleural haemorrhage		
subjects affected / exposed	0 / 9539 (0.00%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Pleurisy		
subjects affected / exposed	2 / 9539 (0.02%)	7 / 9544 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia aspiration		
subjects affected / exposed	7 / 9539 (0.07%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 7	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Pneumonitis		
subjects affected / exposed	2 / 9539 (0.02%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumothorax		

subjects affected / exposed	2 / 9539 (0.02%)	6 / 9544 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary arterial hypertension		
subjects affected / exposed	0 / 9539 (0.00%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary artery thrombosis		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary congestion		
subjects affected / exposed	0 / 9539 (0.00%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary embolism		
subjects affected / exposed	15 / 9539 (0.16%)	24 / 9544 (0.25%)
occurrences causally related to treatment / all	0 / 15	0 / 24
deaths causally related to treatment / all	0 / 5	0 / 8
Pulmonary fibrosis		
subjects affected / exposed	4 / 9539 (0.04%)	5 / 9544 (0.05%)
occurrences causally related to treatment / all	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 0
Pulmonary granuloma		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary hypertension		
subjects affected / exposed	19 / 9539 (0.20%)	10 / 9544 (0.10%)
occurrences causally related to treatment / all	0 / 19	0 / 10
deaths causally related to treatment / all	0 / 2	0 / 0
Pulmonary mass		

subjects affected / exposed	1 / 9539 (0.01%)	4 / 9544 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary microemboli		
subjects affected / exposed	2 / 9539 (0.02%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Pulmonary oedema		
subjects affected / exposed	15 / 9539 (0.16%)	12 / 9544 (0.13%)
occurrences causally related to treatment / all	0 / 16	0 / 12
deaths causally related to treatment / all	0 / 1	0 / 0
Pulmonary thrombosis		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Reflux laryngitis		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Respiration abnormal		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory acidosis		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory arrest		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Respiratory disorder		

subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory distress		
subjects affected / exposed	0 / 9539 (0.00%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory failure		
subjects affected / exposed	21 / 9539 (0.22%)	27 / 9544 (0.28%)
occurrences causally related to treatment / all	0 / 21	0 / 28
deaths causally related to treatment / all	0 / 5	0 / 6
Sinus polyp		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sleep apnoea syndrome		
subjects affected / exposed	7 / 9539 (0.07%)	5 / 9544 (0.05%)
occurrences causally related to treatment / all	0 / 7	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Snoring		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Status asthmaticus		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tachypnoea		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vocal cord polyp		

subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wheezing			
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Acute psychosis			
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Aggression			
subjects affected / exposed	3 / 9539 (0.03%)	2 / 9544 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Agitated depression			
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Agitation			
subjects affected / exposed	2 / 9539 (0.02%)	0 / 9544 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol abuse			
subjects affected / exposed	2 / 9539 (0.02%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol withdrawal syndrome			
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcoholism			

subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Anxiety		
subjects affected / exposed	4 / 9539 (0.04%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Bipolar I disorder		
subjects affected / exposed	0 / 9539 (0.00%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Bipolar disorder		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Completed suicide		
subjects affected / exposed	0 / 9539 (0.00%)	4 / 9544 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 4
Confusional state		
subjects affected / exposed	7 / 9539 (0.07%)	10 / 9544 (0.10%)
occurrences causally related to treatment / all	1 / 7	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Delirium		
subjects affected / exposed	8 / 9539 (0.08%)	7 / 9544 (0.07%)
occurrences causally related to treatment / all	0 / 9	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Delirium tremens		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Delusional disorder, unspecified type		

subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Depressed mood		
subjects affected / exposed	3 / 9539 (0.03%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	1 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Depression		
subjects affected / exposed	57 / 9539 (0.60%)	54 / 9544 (0.57%)
occurrences causally related to treatment / all	0 / 59	0 / 54
deaths causally related to treatment / all	0 / 0	0 / 0
Depression suicidal		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Depressive symptom		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Disorientation		
subjects affected / exposed	1 / 9539 (0.01%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Dysthymic disorder		
subjects affected / exposed	1 / 9539 (0.01%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Hallucination		
subjects affected / exposed	2 / 9539 (0.02%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hallucination, auditory		

subjects affected / exposed	0 / 9539 (0.00%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hallucination, visual		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hallucinations, mixed		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Impulsive behaviour		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Insomnia		
subjects affected / exposed	2 / 9539 (0.02%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intentional drug misuse		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Major depression		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Mood disorder due to a general medical condition		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Nervousness		

subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Obsessive thoughts			
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Panic attack			
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paranoia			
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Persecutory delusion			
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychomotor retardation			
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychosomatic disease			
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychotic disorder due to a general medical condition			
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychotic disorder			

subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Sleep disorder			
subjects affected / exposed	2 / 9539 (0.02%)	0 / 9544 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sleep terror			
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stress			
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicidal ideation			
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicide attempt			
subjects affected / exposed	1 / 9539 (0.01%)	3 / 9544 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Acute hepatic failure			
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Alcoholic liver disease			
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile duct stone			

subjects affected / exposed	4 / 9539 (0.04%)	4 / 9544 (0.04%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 1
Biliary cirrhosis primary		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Biliary colic		
subjects affected / exposed	1 / 9539 (0.01%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Biliary tract disorder		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cholangitis		
subjects affected / exposed	2 / 9539 (0.02%)	6 / 9544 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Cholecystitis		
subjects affected / exposed	9 / 9539 (0.09%)	10 / 9544 (0.10%)
occurrences causally related to treatment / all	0 / 10	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Cholangitis acute		
subjects affected / exposed	0 / 9539 (0.00%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cholecystitis acute		
subjects affected / exposed	19 / 9539 (0.20%)	17 / 9544 (0.18%)
occurrences causally related to treatment / all	0 / 19	0 / 17
deaths causally related to treatment / all	0 / 0	0 / 0
Cholecystitis chronic		

subjects affected / exposed	7 / 9539 (0.07%)	4 / 9544 (0.04%)
occurrences causally related to treatment / all	0 / 7	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Cholelithiasis		
subjects affected / exposed	12 / 9539 (0.13%)	20 / 9544 (0.21%)
occurrences causally related to treatment / all	0 / 12	0 / 20
deaths causally related to treatment / all	0 / 0	0 / 1
Cholestasis		
subjects affected / exposed	0 / 9539 (0.00%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic hepatitis		
subjects affected / exposed	2 / 9539 (0.02%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cirrhosis alcoholic		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Drug-induced liver injury		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gallbladder perforation		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gallbladder polyp		
subjects affected / exposed	0 / 9539 (0.00%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic cirrhosis		

subjects affected / exposed	7 / 9539 (0.07%)	4 / 9544 (0.04%)
occurrences causally related to treatment / all	0 / 8	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 1
Hepatic congestion		
subjects affected / exposed	1 / 9539 (0.01%)	4 / 9544 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic cyst		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic failure		
subjects affected / exposed	0 / 9539 (0.00%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Hepatic mass		
subjects affected / exposed	0 / 9539 (0.00%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic steatosis		
subjects affected / exposed	1 / 9539 (0.01%)	2 / 9544 (0.02%)
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 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatitis alcoholic		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatitis cholestatic		

subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatomegaly		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperbilirubinaemia		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ischaemic hepatitis		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Jaundice		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Jaundice cholestatic		
subjects affected / exposed	2 / 9539 (0.02%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Liver disorder		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Liver injury		
subjects affected / exposed	3 / 9539 (0.03%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Portal vein thrombosis		

subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sphincter of Oddi dysfunction			
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post cholecystectomy syndrome			
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	11 / 9539 (0.12%)	11 / 9544 (0.12%)	
occurrences causally related to treatment / all	0 / 11	1 / 11	
deaths causally related to treatment / all	0 / 0	0 / 1	
Amylase increased			
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriogram carotid			
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriogram coronary			
subjects affected / exposed	43 / 9539 (0.45%)	53 / 9544 (0.56%)	
occurrences causally related to treatment / all	0 / 45	0 / 58	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthroscopy			
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aspartate aminotransferase increased			

subjects affected / exposed	12 / 9539 (0.13%)	10 / 9544 (0.10%)
occurrences causally related to treatment / all	0 / 12	1 / 10
deaths causally related to treatment / all	0 / 0	0 / 1
Biopsy prostate		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Blood alkaline phosphatase increased		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Blood creatine phosphokinase increased		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Blood creatinine increased		
subjects affected / exposed	3 / 9539 (0.03%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Blood glucose decreased		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (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	2 / 9539 (0.02%)	6 / 9544 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Blood iron decreased		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Blood lactate dehydrogenase increased		

subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Blood parathyroid hormone decreased		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Blood potassium decreased		
subjects affected / exposed	0 / 9539 (0.00%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Blood potassium increased		
subjects affected / exposed	4 / 9539 (0.04%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Blood pressure decreased		
subjects affected / exposed	2 / 9539 (0.02%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Blood pressure increased		
subjects affected / exposed	24 / 9539 (0.25%)	13 / 9544 (0.14%)
occurrences causally related to treatment / all	0 / 26	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0
Blood pressure systolic decreased		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Blood pressure systolic increased		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Blood triglycerides increased		

subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Body temperature increased		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
C-reactive protein increased		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac enzymes increased		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Carbohydrate antigen 19-9 increased		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac stress test abnormal		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiovascular evaluation		
subjects affected / exposed	78 / 9539 (0.82%)	84 / 9544 (0.88%)
occurrences causally related to treatment / all	0 / 98	0 / 100
deaths causally related to treatment / all	0 / 0	0 / 0
Catheterisation cardiac		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cystoscopy normal		

subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Chest X-ray abnormal		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
ECG signs of myocardial ischaemia		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ejection fraction decreased		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Electrocardiogram QT prolonged		
subjects affected / exposed	57 / 9539 (0.60%)	18 / 9544 (0.19%)
occurrences causally related to treatment / all	42 / 60	6 / 18
deaths causally related to treatment / all	0 / 0	0 / 0
Electrocardiogram ST segment depression		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Electrocardiogram ST segment elevation		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Electrocardiogram T wave inversion		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Electrocardiogram ambulatory		

subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Electrocardiogram change		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Electrocardiogram repolarisation abnormality		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Fibrin D dimer increased		
subjects affected / exposed	0 / 9539 (0.00%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gamma-glutamyltransferase increased		
subjects affected / exposed	2 / 9539 (0.02%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal examination		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Haemoglobin decreased		
subjects affected / exposed	2 / 9539 (0.02%)	6 / 9544 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Heart rate decreased		
subjects affected / exposed	55 / 9539 (0.58%)	7 / 9544 (0.07%)
occurrences causally related to treatment / all	40 / 55	4 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic enzyme increased		

subjects affected / exposed	2 / 9539 (0.02%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
International normalised ratio increased			
subjects affected / exposed	1 / 9539 (0.01%)	3 / 9544 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intraocular pressure increased			
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigation			
subjects affected / exposed	7 / 9539 (0.07%)	6 / 9544 (0.06%)	
occurrences causally related to treatment / all	0 / 7	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oxygen saturation decreased			
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Platelet count decreased			
subjects affected / exposed	2 / 9539 (0.02%)	0 / 9544 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary arterial pressure increased			
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Red blood cell sedimentation rate increased			
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Romberg test positive			

subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sleep study		
subjects affected / exposed	3 / 9539 (0.03%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Streptococcus test positive		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Stress echocardiogram abnormal		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Thyroid function test abnormal		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Treponema test positive		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Troponin increased		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Weight decreased		
subjects affected / exposed	5 / 9539 (0.05%)	11 / 9544 (0.12%)
occurrences causally related to treatment / all	0 / 5	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
White blood cell count increased		

subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Abdominal injury			
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal wound dehiscence			
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Accident			
subjects affected / exposed	0 / 9539 (0.00%)	2 / 9544 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Accident at home			
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Accidental overdose			
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Agitation postoperative			
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol poisoning			
subjects affected / exposed	0 / 9539 (0.00%)	3 / 9544 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia postoperative			

subjects affected / exposed	2 / 9539 (0.02%)	4 / 9544 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Ankle fracture		
subjects affected / exposed	6 / 9539 (0.06%)	8 / 9544 (0.08%)
occurrences causally related to treatment / all	0 / 6	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic injury		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Arterial restenosis		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Arthropod sting		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Asbestosis		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Back injury		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Blindness traumatic		
subjects affected / exposed	2 / 9539 (0.02%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bone fissure		

subjects affected / exposed	1 / 9539 (0.01%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Brain contusion		
subjects affected / exposed	4 / 9539 (0.04%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Burns second degree		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Carbon monoxide poisoning		
subjects affected / exposed	0 / 9539 (0.00%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Cardiac contusion		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac procedure complication		
subjects affected / exposed	0 / 9539 (0.00%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac valve replacement complication		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac valve rupture		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Carotid artery restenosis		

subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cervical vertebral fracture		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Chest injury		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Clavicle fracture		
subjects affected / exposed	1 / 9539 (0.01%)	4 / 9544 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Concussion		
subjects affected / exposed	6 / 9539 (0.06%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	0 / 6	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Contusion		
subjects affected / exposed	9 / 9539 (0.09%)	8 / 9544 (0.08%)
occurrences causally related to treatment / all	0 / 9	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery restenosis		
subjects affected / exposed	9 / 9539 (0.09%)	12 / 9544 (0.13%)
occurrences causally related to treatment / all	0 / 9	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0
Corrosive gastritis		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Craniocerebral injury		

subjects affected / exposed	2 / 9539 (0.02%)	5 / 9544 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Crushing injury of trunk		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Extradural haematoma		
subjects affected / exposed	0 / 9539 (0.00%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Eye contusion		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Eye injury		
subjects affected / exposed	3 / 9539 (0.03%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Face injury		
subjects affected / exposed	2 / 9539 (0.02%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Facial bones fracture		
subjects affected / exposed	1 / 9539 (0.01%)	4 / 9544 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Febrile nonhaemolytic transfusion reaction		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Fall		

subjects affected / exposed	95 / 9539 (1.00%)	109 / 9544 (1.14%)
occurrences causally related to treatment / all	4 / 96	2 / 109
deaths causally related to treatment / all	0 / 0	0 / 0
Femoral neck fracture		
subjects affected / exposed	13 / 9539 (0.14%)	12 / 9544 (0.13%)
occurrences causally related to treatment / all	0 / 13	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0
Femur fracture		
subjects affected / exposed	15 / 9539 (0.16%)	10 / 9544 (0.10%)
occurrences causally related to treatment / all	0 / 15	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Fibula fracture		
subjects affected / exposed	4 / 9539 (0.04%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Foot fracture		
subjects affected / exposed	5 / 9539 (0.05%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Foreign body		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Forearm fracture		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Foreign body in eye		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (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	3 / 9539 (0.03%)	4 / 9544 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Head injury		
subjects affected / exposed	4 / 9539 (0.04%)	10 / 9544 (0.10%)
occurrences causally related to treatment / all	1 / 4	2 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Heat stroke		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hip fracture		
subjects affected / exposed	6 / 9539 (0.06%)	6 / 9544 (0.06%)
occurrences causally related to treatment / all	0 / 6	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Humerus fracture		
subjects affected / exposed	4 / 9539 (0.04%)	5 / 9544 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Ilium fracture		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Incisional hernia		
subjects affected / exposed	0 / 9539 (0.00%)	4 / 9544 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Intentional overdose		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Injury		

subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral disc injury		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal anastomosis complication		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Jaw fracture		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Joint dislocation		
subjects affected / exposed	4 / 9539 (0.04%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Joint dislocation postoperative		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Joint injury		
subjects affected / exposed	1 / 9539 (0.01%)	4 / 9544 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Kidney rupture		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Laceration		

subjects affected / exposed	2 / 9539 (0.02%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ligament rupture		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ligament sprain		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Limb crushing injury		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Limb injury		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Limb traumatic amputation		
subjects affected / exposed	2 / 9539 (0.02%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lip injury		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (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	4 / 9539 (0.04%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Lumbar vertebral fracture		

subjects affected / exposed	4 / 9539 (0.04%)	6 / 9544 (0.06%)
occurrences causally related to treatment / all	0 / 4	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 1
Meniscus injury		
subjects affected / exposed	2 / 9539 (0.02%)	6 / 9544 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Multiple fractures		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Multiple injuries		
subjects affected / exposed	2 / 9539 (0.02%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 2	0 / 1
Muscle rupture		
subjects affected / exposed	0 / 9539 (0.00%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Neck injury		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Osteoradionecrosis		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatic injury		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pelvic fracture		

subjects affected / exposed	1 / 9539 (0.01%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Penetrating abdominal trauma		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Periorbital haematoma		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery restenosis		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumoconiosis		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumothorax traumatic		
subjects affected / exposed	2 / 9539 (0.02%)	5 / 9544 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural contusion		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural complication		
subjects affected / exposed	2 / 9539 (0.02%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
Post procedural fistula		

subjects affected / exposed	0 / 9539 (0.00%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural haematoma		
subjects affected / exposed	3 / 9539 (0.03%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural haematuria		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural hypothyroidism		
subjects affected / exposed	0 / 9539 (0.00%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural haemorrhage		
subjects affected / exposed	3 / 9539 (0.03%)	4 / 9544 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 1
Post procedural myocardial infarction		
subjects affected / exposed	14 / 9539 (0.15%)	13 / 9544 (0.14%)
occurrences causally related to treatment / all	0 / 14	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 1
Post procedural pulmonary embolism		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post-thoracotomy pain syndrome		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post-traumatic pain		

subjects affected / exposed	1 / 9539 (0.01%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	1 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative thoracic procedure complication		
subjects affected / exposed	1 / 9539 (0.01%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative ileus		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative wound complication		
subjects affected / exposed	2 / 9539 (0.02%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Procedural haemorrhage		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Procedural hypertension		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Procedural hypotension		
subjects affected / exposed	2 / 9539 (0.02%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Procedural pain		
subjects affected / exposed	2 / 9539 (0.02%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Procedural site reaction		

subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (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 / 9539 (0.01%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Radiation oesophagitis		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Radius fracture		
subjects affected / exposed	8 / 9539 (0.08%)	15 / 9544 (0.16%)
occurrences causally related to treatment / all	0 / 8	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0
Renal haematoma		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (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	23 / 9539 (0.24%)	26 / 9544 (0.27%)
occurrences causally related to treatment / all	0 / 23	0 / 26
deaths causally related to treatment / all	0 / 2	0 / 1
Rib fracture		
subjects affected / exposed	8 / 9539 (0.08%)	15 / 9544 (0.16%)
occurrences causally related to treatment / all	0 / 8	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0
Seroma		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Shunt thrombosis		

subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Silicosis		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Skull fracture		
subjects affected / exposed	2 / 9539 (0.02%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Skull fractured base		
subjects affected / exposed	2 / 9539 (0.02%)	4 / 9544 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal column injury		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal compression fracture		
subjects affected / exposed	3 / 9539 (0.03%)	4 / 9544 (0.04%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal fracture		
subjects affected / exposed	5 / 9539 (0.05%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Splenic rupture		
subjects affected / exposed	1 / 9539 (0.01%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Stab wound		

subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sternal fracture		
subjects affected / exposed	2 / 9539 (0.02%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Subcutaneous haematoma		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Subdural haematoma		
subjects affected / exposed	8 / 9539 (0.08%)	7 / 9544 (0.07%)
occurrences causally related to treatment / all	0 / 8	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Subdural haemorrhage		
subjects affected / exposed	1 / 9539 (0.01%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Suture related complication		
subjects affected / exposed	2 / 9539 (0.02%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tendon injury		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tendon rupture		
subjects affected / exposed	1 / 9539 (0.01%)	6 / 9544 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Thoracic vertebral fracture		

subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tibia fracture		
subjects affected / exposed	6 / 9539 (0.06%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	0 / 6	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Tongue injury		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Toxicity to various agents		
subjects affected / exposed	1 / 9539 (0.01%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Transfusion reaction		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Traumatic haematoma		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Traumatic intracranial haemorrhage		
subjects affected / exposed	3 / 9539 (0.03%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Traumatic ulcer		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ulna fracture		

subjects affected / exposed	2 / 9539 (0.02%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Upper limb fracture		
subjects affected / exposed	3 / 9539 (0.03%)	4 / 9544 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular graft complication		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular graft occlusion		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular graft thrombosis		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vasoplegia syndrome		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular pseudoaneurysm		
subjects affected / exposed	4 / 9539 (0.04%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Wound complication		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Wound necrosis		

subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wrist fracture			
subjects affected / exposed	2 / 9539 (0.02%)	3 / 9544 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital, familial and genetic disorders			
Adenomatous polyposis coli			
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital umbilical hernia			
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Factor V Leiden mutation			
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolic myopathy			
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyloric stenosis			
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Accelerated idioventricular rhythm			
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Acute coronary syndrome		
subjects affected / exposed	17 / 9539 (0.18%)	21 / 9544 (0.22%)
occurrences causally related to treatment / all	1 / 18	0 / 24
deaths causally related to treatment / all	0 / 4	0 / 1
Acute left ventricular failure		
subjects affected / exposed	2 / 9539 (0.02%)	5 / 9544 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 1
Acute myocardial infarction		
subjects affected / exposed	200 / 9539 (2.10%)	208 / 9544 (2.18%)
occurrences causally related to treatment / all	2 / 216	0 / 229
deaths causally related to treatment / all	0 / 23	0 / 23
Adams-Stokes syndrome		
subjects affected / exposed	0 / 9539 (0.00%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	0 / 0	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Angina pectoris		
subjects affected / exposed	294 / 9539 (3.08%)	330 / 9544 (3.46%)
occurrences causally related to treatment / all	3 / 314	2 / 361
deaths causally related to treatment / all	0 / 1	0 / 0
Angina unstable		
subjects affected / exposed	409 / 9539 (4.29%)	433 / 9544 (4.54%)
occurrences causally related to treatment / all	4 / 479	0 / 524
deaths causally related to treatment / all	0 / 2	0 / 0
Aortic valve disease		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic valve disease mixed		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic valve incompetence		

subjects affected / exposed	3 / 9539 (0.03%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic valve sclerosis		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Arrhythmia		
subjects affected / exposed	2 / 9539 (0.02%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0
Aortic valve stenosis		
subjects affected / exposed	12 / 9539 (0.13%)	9 / 9544 (0.09%)
occurrences causally related to treatment / all	0 / 12	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Arrhythmia supraventricular		
subjects affected / exposed	2 / 9539 (0.02%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	1 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Arteriosclerosis coronary artery		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Arteriospasm coronary		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Atrial flutter		
subjects affected / exposed	49 / 9539 (0.51%)	41 / 9544 (0.43%)
occurrences causally related to treatment / all	0 / 52	0 / 45
deaths causally related to treatment / all	0 / 0	0 / 0
Atrial fibrillation		

subjects affected / exposed	336 / 9539 (3.52%)	232 / 9544 (2.43%)
occurrences causally related to treatment / all	22 / 381	2 / 262
deaths causally related to treatment / all	0 / 0	0 / 0
Atrial tachycardia		
subjects affected / exposed	4 / 9539 (0.04%)	5 / 9544 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Atrioventricular block		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Atrioventricular block complete		
subjects affected / exposed	17 / 9539 (0.18%)	13 / 9544 (0.14%)
occurrences causally related to treatment / all	4 / 17	1 / 13
deaths causally related to treatment / all	0 / 0	0 / 0
Atrioventricular block first degree		
subjects affected / exposed	4 / 9539 (0.04%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	2 / 4	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Atrioventricular block second degree		
subjects affected / exposed	22 / 9539 (0.23%)	13 / 9544 (0.14%)
occurrences causally related to treatment / all	10 / 22	7 / 13
deaths causally related to treatment / all	0 / 0	0 / 0
Atrioventricular dissociation		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bradycardia		
subjects affected / exposed	101 / 9539 (1.06%)	21 / 9544 (0.22%)
occurrences causally related to treatment / all	91 / 102	15 / 21
deaths causally related to treatment / all	0 / 0	0 / 0
Bundle branch block		

subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bundle branch block left		
subjects affected / exposed	7 / 9539 (0.07%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 7	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac aneurysm		
subjects affected / exposed	5 / 9539 (0.05%)	9 / 9544 (0.09%)
occurrences causally related to treatment / all	0 / 5	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac arrest		
subjects affected / exposed	15 / 9539 (0.16%)	8 / 9544 (0.08%)
occurrences causally related to treatment / all	0 / 16	0 / 8
deaths causally related to treatment / all	0 / 1	0 / 1
Cardiac asthma		
subjects affected / exposed	2 / 9539 (0.02%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
Cardiac failure		
subjects affected / exposed	357 / 9539 (3.74%)	346 / 9544 (3.63%)
occurrences causally related to treatment / all	13 / 415	2 / 394
deaths causally related to treatment / all	0 / 16	0 / 14
Cardiac failure acute		
subjects affected / exposed	37 / 9539 (0.39%)	23 / 9544 (0.24%)
occurrences causally related to treatment / all	0 / 45	0 / 26
deaths causally related to treatment / all	0 / 7	0 / 9
Cardiac failure congestive		
subjects affected / exposed	31 / 9539 (0.32%)	24 / 9544 (0.25%)
occurrences causally related to treatment / all	0 / 33	0 / 26
deaths causally related to treatment / all	0 / 0	0 / 2
Cardiac failure chronic		

subjects affected / exposed	25 / 9539 (0.26%)	29 / 9544 (0.30%)
occurrences causally related to treatment / all	1 / 28	0 / 36
deaths causally related to treatment / all	0 / 1	0 / 1
Cardiac tamponade		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardio-respiratory arrest		
subjects affected / exposed	3 / 9539 (0.03%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiogenic shock		
subjects affected / exposed	30 / 9539 (0.31%)	22 / 9544 (0.23%)
occurrences causally related to treatment / all	0 / 30	0 / 22
deaths causally related to treatment / all	0 / 12	0 / 9
Cardiomegaly		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiopulmonary failure		
subjects affected / exposed	3 / 9539 (0.03%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
Cardiomyopathy		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiovascular insufficiency		
subjects affected / exposed	1 / 9539 (0.01%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 2
Congestive cardiomyopathy		

subjects affected / exposed	2 / 9539 (0.02%)	4 / 9544 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 1
Cor pulmonale		
subjects affected / exposed	6 / 9539 (0.06%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Coronary artery disease		
subjects affected / exposed	20 / 9539 (0.21%)	25 / 9544 (0.26%)
occurrences causally related to treatment / all	0 / 21	0 / 25
deaths causally related to treatment / all	0 / 0	0 / 0
Cor pulmonale chronic		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery dissection		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery insufficiency		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery occlusion		
subjects affected / exposed	14 / 9539 (0.15%)	7 / 9544 (0.07%)
occurrences causally related to treatment / all	0 / 14	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery stenosis		
subjects affected / exposed	18 / 9539 (0.19%)	26 / 9544 (0.27%)
occurrences causally related to treatment / all	0 / 19	0 / 26
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery thrombosis		

subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dressler's syndrome		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Endocarditis noninfective		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Heart valve incompetence		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
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	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intracardiac thrombus		
subjects affected / exposed	5 / 9539 (0.05%)	9 / 9544 (0.09%)
occurrences causally related to treatment / all	0 / 5	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Ischaemic cardiomyopathy		
subjects affected / exposed	3 / 9539 (0.03%)	6 / 9544 (0.06%)
occurrences causally related to treatment / all	0 / 5	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Left atrial dilatation		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Left ventricular dysfunction		

subjects affected / exposed	1 / 9539 (0.01%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Left ventricular failure		
subjects affected / exposed	9 / 9539 (0.09%)	10 / 9544 (0.10%)
occurrences causally related to treatment / all	0 / 10	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 1
Left ventricular hypertrophy		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Low cardiac output syndrome		
subjects affected / exposed	1 / 9539 (0.01%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	1 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Mitral valve incompetence		
subjects affected / exposed	16 / 9539 (0.17%)	14 / 9544 (0.15%)
occurrences causally related to treatment / all	0 / 16	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0
Mitral valve prolapse		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Myocardial depression		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Myocardial fibrosis		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Myocardial infarction		

subjects affected / exposed	98 / 9539 (1.03%)	83 / 9544 (0.87%)
occurrences causally related to treatment / all	0 / 104	0 / 88
deaths causally related to treatment / all	0 / 15	0 / 14
Myocardial ischaemia		
subjects affected / exposed	23 / 9539 (0.24%)	27 / 9544 (0.28%)
occurrences causally related to treatment / all	0 / 23	0 / 27
deaths causally related to treatment / all	0 / 1	0 / 0
Myocarditis		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nodal arrhythmia		
subjects affected / exposed	1 / 9539 (0.01%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Nodal rhythm		
subjects affected / exposed	5 / 9539 (0.05%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	1 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Palpitations		
subjects affected / exposed	2 / 9539 (0.02%)	4 / 9544 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Pericardial effusion		
subjects affected / exposed	1 / 9539 (0.01%)	5 / 9544 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Pericarditis		
subjects affected / exposed	3 / 9539 (0.03%)	8 / 9544 (0.08%)
occurrences causally related to treatment / all	0 / 3	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Postinfarction angina		

subjects affected / exposed	1 / 9539 (0.01%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Prinzmetal angina		
subjects affected / exposed	0 / 9539 (0.00%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Rhythm idioventricular		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Right ventricular failure		
subjects affected / exposed	8 / 9539 (0.08%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 8	0 / 1
deaths causally related to treatment / all	0 / 2	0 / 0
Sick sinus syndrome		
subjects affected / exposed	9 / 9539 (0.09%)	5 / 9544 (0.05%)
occurrences causally related to treatment / all	4 / 9	4 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Silent myocardial infarction		
subjects affected / exposed	5 / 9539 (0.05%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Sinoatrial block		
subjects affected / exposed	0 / 9539 (0.00%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	0 / 0	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Sinus arrest		
subjects affected / exposed	9 / 9539 (0.09%)	9 / 9544 (0.09%)
occurrences causally related to treatment / all	8 / 9	4 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Sinus arrhythmia		

subjects affected / exposed	2 / 9539 (0.02%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	2 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sinus bradycardia		
subjects affected / exposed	48 / 9539 (0.50%)	7 / 9544 (0.07%)
occurrences causally related to treatment / all	42 / 49	4 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Sinus tachycardia		
subjects affected / exposed	6 / 9539 (0.06%)	12 / 9544 (0.13%)
occurrences causally related to treatment / all	0 / 6	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0
Supraventricular extrasystoles		
subjects affected / exposed	8 / 9539 (0.08%)	15 / 9544 (0.16%)
occurrences causally related to treatment / all	1 / 8	2 / 15
deaths causally related to treatment / all	0 / 0	0 / 0
Supraventricular tachycardia		
subjects affected / exposed	17 / 9539 (0.18%)	21 / 9544 (0.22%)
occurrences causally related to treatment / all	1 / 18	0 / 24
deaths causally related to treatment / all	0 / 0	0 / 0
Supraventricular tachyarrhythmia		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tachyarrhythmia		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tachycardia		
subjects affected / exposed	2 / 9539 (0.02%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Torsade de pointes		

subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tricuspid valve incompetence		
subjects affected / exposed	6 / 9539 (0.06%)	5 / 9544 (0.05%)
occurrences causally related to treatment / all	0 / 6	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Trifascicular block		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ventricular arrhythmia		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Ventricular extrasystoles		
subjects affected / exposed	32 / 9539 (0.34%)	21 / 9544 (0.22%)
occurrences causally related to treatment / all	2 / 32	2 / 21
deaths causally related to treatment / all	0 / 0	0 / 0
Ventricular failure		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Ventricular fibrillation		
subjects affected / exposed	20 / 9539 (0.21%)	20 / 9544 (0.21%)
occurrences causally related to treatment / all	0 / 20	0 / 22
deaths causally related to treatment / all	0 / 1	0 / 6
Ventricular tachycardia		
subjects affected / exposed	35 / 9539 (0.37%)	21 / 9544 (0.22%)
occurrences causally related to treatment / all	3 / 39	0 / 23
deaths causally related to treatment / all	0 / 1	0 / 0
Wolff-Parkinson-White syndrome		

subjects affected / exposed	0 / 9539 (0.00%)	2 / 9544 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Amnesia			
subjects affected / exposed	5 / 9539 (0.05%)	2 / 9544 (0.02%)	
occurrences causally related to treatment / all	1 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Altered state of consciousness			
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Amyotrophic lateral sclerosis			
subjects affected / exposed	0 / 9539 (0.00%)	2 / 9544 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anticholinergic syndrome			
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aphasia			
subjects affected / exposed	2 / 9539 (0.02%)	3 / 9544 (0.03%)	
occurrences causally related to treatment / all	1 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ataxia			
subjects affected / exposed	1 / 9539 (0.01%)	2 / 9544 (0.02%)	
occurrences causally related to treatment / all	0 / 1	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Autonomic neuropathy			
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Balance disorder			

subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Brain hypoxia		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Brain injury		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Brain oedema		
subjects affected / exposed	1 / 9539 (0.01%)	4 / 9544 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Brain stem infarction		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Carotid aneurysm rupture		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Carotid arteriosclerosis		
subjects affected / exposed	4 / 9539 (0.04%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Carotid artery aneurysm		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Carotid artery disease		

subjects affected / exposed	2 / 9539 (0.02%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Carotid artery dissection		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Carotid artery occlusion		
subjects affected / exposed	3 / 9539 (0.03%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Carotid artery stenosis		
subjects affected / exposed	51 / 9539 (0.53%)	43 / 9544 (0.45%)
occurrences causally related to treatment / all	0 / 57	0 / 45
deaths causally related to treatment / all	0 / 0	0 / 0
Carotid sinus syndrome		
subjects affected / exposed	0 / 9539 (0.00%)	4 / 9544 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Carpal tunnel syndrome		
subjects affected / exposed	4 / 9539 (0.04%)	6 / 9544 (0.06%)
occurrences causally related to treatment / all	0 / 4	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebellar atrophy		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebellar haemorrhage		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Cerebellar ischaemia		

subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebellar syndrome		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral arteriosclerosis		
subjects affected / exposed	1 / 9539 (0.01%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral artery stenosis		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral atrophy		
subjects affected / exposed	4 / 9539 (0.04%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral haematoma		
subjects affected / exposed	2 / 9539 (0.02%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral haemorrhage		
subjects affected / exposed	3 / 9539 (0.03%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 1
Cerebral infarction		
subjects affected / exposed	15 / 9539 (0.16%)	13 / 9544 (0.14%)
occurrences causally related to treatment / all	0 / 15	0 / 13
deaths causally related to treatment / all	0 / 1	0 / 1
Cerebral ischaemia		

subjects affected / exposed	8 / 9539 (0.08%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	0 / 9	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral microangiopathy		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebrovascular accident		
subjects affected / exposed	31 / 9539 (0.32%)	40 / 9544 (0.42%)
occurrences causally related to treatment / all	0 / 32	0 / 44
deaths causally related to treatment / all	0 / 5	0 / 5
Cerebrovascular disorder		
subjects affected / exposed	5 / 9539 (0.05%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebrovascular insufficiency		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cervical cord compression		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cervical myelopathy		
subjects affected / exposed	0 / 9539 (0.00%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cervicobrachial syndrome		
subjects affected / exposed	1 / 9539 (0.01%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cognitive disorder		

subjects affected / exposed	1 / 9539 (0.01%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Coma		
subjects affected / exposed	2 / 9539 (0.02%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0
Convulsion		
subjects affected / exposed	1 / 9539 (0.01%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	1 / 1	0 / 2
deaths causally related to treatment / all	1 / 1	0 / 0
Coordination abnormal		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cranial nerve disorder		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cranial nerve paralysis		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cubital tunnel syndrome		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dementia		
subjects affected / exposed	4 / 9539 (0.04%)	4 / 9544 (0.04%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Dementia Alzheimer's type		

subjects affected / exposed	2 / 9539 (0.02%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dementia of the Alzheimer's type, with delusions		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Demyelinating polyneuropathy		
subjects affected / exposed	1 / 9539 (0.01%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Depressed level of consciousness		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic hyperglycaemic coma		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Diabetic neuropathy		
subjects affected / exposed	10 / 9539 (0.10%)	10 / 9544 (0.10%)
occurrences causally related to treatment / all	0 / 10	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Dizziness		
subjects affected / exposed	19 / 9539 (0.20%)	18 / 9544 (0.19%)
occurrences causally related to treatment / all	3 / 19	3 / 20
deaths causally related to treatment / all	0 / 0	0 / 0
Dizziness postural		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Drop attacks		

subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dysarthria		
subjects affected / exposed	2 / 9539 (0.02%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 2	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Dystonic tremor		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Encephalitis		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Encephalomyelitis		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Encephalopathy		
subjects affected / exposed	4 / 9539 (0.04%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Epilepsy		
subjects affected / exposed	7 / 9539 (0.07%)	5 / 9544 (0.05%)
occurrences causally related to treatment / all	0 / 9	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Essential tremor		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Extrapyramidal disorder		

subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Facial nerve disorder		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Grand mal convulsion		
subjects affected / exposed	4 / 9539 (0.04%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Facial paresis		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Guillain-Barre syndrome		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
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 / 9539 (0.00%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhagic stroke		
subjects affected / exposed	5 / 9539 (0.05%)	12 / 9544 (0.13%)
occurrences causally related to treatment / all	0 / 6	0 / 12
deaths causally related to treatment / all	0 / 4	0 / 5
Headache		
subjects affected / exposed	5 / 9539 (0.05%)	8 / 9544 (0.08%)
occurrences causally related to treatment / all	0 / 5	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Hemianopia homonymous		

subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (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	6 / 9539 (0.06%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 7	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Horner's syndrome		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hydrocephalus		
subjects affected / exposed	2 / 9539 (0.02%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertensive encephalopathy		
subjects affected / exposed	2 / 9539 (0.02%)	6 / 9544 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoaesthesia		
subjects affected / exposed	3 / 9539 (0.03%)	9 / 9544 (0.09%)
occurrences causally related to treatment / all	1 / 3	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoglycaemic coma		
subjects affected / exposed	2 / 9539 (0.02%)	5 / 9544 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 0
Hypoglycaemic unconsciousness		
subjects affected / exposed	4 / 9539 (0.04%)	9 / 9544 (0.09%)
occurrences causally related to treatment / all	0 / 4	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Hyporeflexia		

subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoxic-ischaemic encephalopathy		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
IIIrd nerve paralysis		
subjects affected / exposed	1 / 9539 (0.01%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Intercostal neuralgia		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intracranial aneurysm		
subjects affected / exposed	4 / 9539 (0.04%)	5 / 9544 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Intracranial hypotension		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intracranial pressure increased		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intracranial venous sinus thrombosis		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ischaemic cerebral infarction		

subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ischaemic neuropathy		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ischaemic stroke		
subjects affected / exposed	97 / 9539 (1.02%)	90 / 9544 (0.94%)
occurrences causally related to treatment / all	1 / 100	0 / 95
deaths causally related to treatment / all	0 / 13	0 / 6
Lacunar infarction		
subjects affected / exposed	5 / 9539 (0.05%)	6 / 9544 (0.06%)
occurrences causally related to treatment / all	0 / 5	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Lethargy		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Loss of consciousness		
subjects affected / exposed	32 / 9539 (0.34%)	22 / 9544 (0.23%)
occurrences causally related to treatment / all	3 / 32	1 / 22
deaths causally related to treatment / all	0 / 0	0 / 0
Lumbar radiculopathy		
subjects affected / exposed	1 / 9539 (0.01%)	4 / 9544 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Memory impairment		
subjects affected / exposed	4 / 9539 (0.04%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Migraine		

subjects affected / exposed	1 / 9539 (0.01%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Monoplegia		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Movement disorder		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Multiple sclerosis		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Myasthenia gravis		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Myelitis transverse		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Myelopathy		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nerve compression		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nerve root compression		

subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nerve root lesion		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Neuralgia		
subjects affected / exposed	2 / 9539 (0.02%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neuritis cranial		
subjects affected / exposed	0 / 9539 (0.00%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Neurodegenerative disorder		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Neurological decompensation		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neuropathy peripheral		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Normal pressure hydrocephalus		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Paraesthesia		

subjects affected / exposed	1 / 9539 (0.01%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	0 / 1	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Paraplegia		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Parkinson's disease		
subjects affected / exposed	6 / 9539 (0.06%)	8 / 9544 (0.08%)
occurrences causally related to treatment / all	0 / 6	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Parkinsonism		
subjects affected / exposed	2 / 9539 (0.02%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Partial seizures		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral sensorimotor neuropathy		
subjects affected / exposed	0 / 9539 (0.00%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral sensory neuropathy		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Polyneuropathy		
subjects affected / exposed	0 / 9539 (0.00%)	4 / 9544 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Petit mal epilepsy		

subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Poor quality sleep		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post-injection delirium sedation syndrome		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Post-traumatic headache		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Presyncope		
subjects affected / exposed	15 / 9539 (0.16%)	8 / 9544 (0.08%)
occurrences causally related to treatment / all	4 / 15	1 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Posterior reversible encephalopathy syndrome		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Psychomotor hyperactivity		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pyramidal tract syndrome		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Radial nerve compression		

subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Radicular pain		
subjects affected / exposed	0 / 9539 (0.00%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Radicular syndrome		
subjects affected / exposed	2 / 9539 (0.02%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Radiculopathy		
subjects affected / exposed	5 / 9539 (0.05%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Restless legs syndrome		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Retrograde amnesia		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sciatica		
subjects affected / exposed	2 / 9539 (0.02%)	8 / 9544 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Senile dementia		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Speech disorder		

subjects affected / exposed	2 / 9539 (0.02%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Somnolence		
subjects affected / exposed	4 / 9539 (0.04%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	1 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal cord compression		
subjects affected / exposed	2 / 9539 (0.02%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal vascular disorder		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Spondylitic myelopathy		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Subarachnoid haemorrhage		
subjects affected / exposed	5 / 9539 (0.05%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0
Subdural hygroma		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Syncope		
subjects affected / exposed	91 / 9539 (0.95%)	89 / 9544 (0.93%)
occurrences causally related to treatment / all	23 / 102	6 / 96
deaths causally related to treatment / all	0 / 0	0 / 0
Thalamic infarction		

subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Thalamus haemorrhage		
subjects affected / exposed	0 / 9539 (0.00%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Thrombotic stroke		
subjects affected / exposed	0 / 9539 (0.00%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Tonic convulsion		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Transient global amnesia		
subjects affected / exposed	2 / 9539 (0.02%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tremor		
subjects affected / exposed	0 / 9539 (0.00%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	0 / 0	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Transient ischaemic attack		
subjects affected / exposed	56 / 9539 (0.59%)	50 / 9544 (0.52%)
occurrences causally related to treatment / all	3 / 59	0 / 50
deaths causally related to treatment / all	0 / 0	0 / 0
Ulnar neurapraxia		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ulnar tunnel syndrome		

subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
VIIth nerve paralysis		
subjects affected / exposed	1 / 9539 (0.01%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
VIth nerve disorder		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
VIth nerve paralysis		
subjects affected / exposed	0 / 9539 (0.00%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular dementia		
subjects affected / exposed	3 / 9539 (0.03%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular encephalopathy		
subjects affected / exposed	11 / 9539 (0.12%)	9 / 9544 (0.09%)
occurrences causally related to treatment / all	0 / 11	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Vertebral artery occlusion		
subjects affected / exposed	2 / 9539 (0.02%)	0 / 9544 (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	3 / 9539 (0.03%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vertebrobasilar insufficiency		

subjects affected / exposed	15 / 9539 (0.16%)	12 / 9544 (0.13%)	
occurrences causally related to treatment / all	0 / 15	0 / 16	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo CNS origin			
subjects affected / exposed	2 / 9539 (0.02%)	0 / 9544 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vocal cord paresis			
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wernicke-Korsakoff syndrome			
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (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			
Agranulocytosis			
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia			
subjects affected / exposed	30 / 9539 (0.31%)	45 / 9544 (0.47%)	
occurrences causally related to treatment / all	0 / 30	0 / 45	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia folate deficiency			
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia megaloblastic			
subjects affected / exposed	2 / 9539 (0.02%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia vitamin B12 deficiency			

subjects affected / exposed	1 / 9539 (0.01%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Bone marrow failure		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Deficiency anaemia		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Disseminated intravascular coagulation		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Febrile neutropenia		
subjects affected / exposed	2 / 9539 (0.02%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Haemorrhagic diathesis		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (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	14 / 9539 (0.15%)	15 / 9544 (0.16%)
occurrences causally related to treatment / all	0 / 14	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhagic disorder		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Heparin-induced thrombocytopenia		

subjects affected / exposed	2 / 9539 (0.02%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypochromic anaemia		
subjects affected / exposed	8 / 9539 (0.08%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 8	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoprothrombinaemia		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Idiopathic thrombocytopenic purpura		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (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 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Iron deficiency anaemia		
subjects affected / exposed	7 / 9539 (0.07%)	8 / 9544 (0.08%)
occurrences causally related to treatment / all	0 / 7	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Leukopenia		
subjects affected / exposed	2 / 9539 (0.02%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphadenopathy		
subjects affected / exposed	3 / 9539 (0.03%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphadenopathy mediastinal		

subjects affected / exposed	0 / 9539 (0.00%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphopenia		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Microcytic anaemia		
subjects affected / exposed	4 / 9539 (0.04%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Nephrogenic anaemia		
subjects affected / exposed	0 / 9539 (0.00%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Neutropenia		
subjects affected / exposed	3 / 9539 (0.03%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Normochromic normocytic anaemia		
subjects affected / exposed	4 / 9539 (0.04%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pancytopenia		
subjects affected / exposed	4 / 9539 (0.04%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Platelet dysfunction		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sideroblastic anaemia		

subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (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	15 / 9539 (0.16%)	12 / 9544 (0.13%)	
occurrences causally related to treatment / all	0 / 17	1 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombocytopenic purpura			
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombocytosis			
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
Acute vestibular syndrome			
subjects affected / exposed	4 / 9539 (0.04%)	0 / 9544 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deafness neurosensory			
subjects affected / exposed	2 / 9539 (0.02%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deafness unilateral			
subjects affected / exposed	2 / 9539 (0.02%)	0 / 9544 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematotympanum			
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hearing impaired			

subjects affected / exposed	2 / 9539 (0.02%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoacusis		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Meniere's disease		
subjects affected / exposed	0 / 9539 (0.00%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Neurosensory hypoacusis		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sudden hearing loss		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tinnitus		
subjects affected / exposed	3 / 9539 (0.03%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tympanic membrane disorder		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vertigo		
subjects affected / exposed	9 / 9539 (0.09%)	7 / 9544 (0.07%)
occurrences causally related to treatment / all	2 / 9	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Vestibular ataxia		

subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vestibular disorder			
subjects affected / exposed	2 / 9539 (0.02%)	3 / 9544 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Age-related macular degeneration			
subjects affected / exposed	4 / 9539 (0.04%)	4 / 9544 (0.04%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Amaurosis			
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Amaurosis fugax			
subjects affected / exposed	2 / 9539 (0.02%)	4 / 9544 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angle closure glaucoma			
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blindness			
subjects affected / exposed	1 / 9539 (0.01%)	3 / 9544 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cataract			
subjects affected / exposed	39 / 9539 (0.41%)	32 / 9544 (0.34%)	
occurrences causally related to treatment / all	0 / 43	0 / 32	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blindness unilateral			

subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cataract diabetic		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cataract nuclear		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cataract subcapsular		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Choroidal effusion		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Choroidal neovascularisation		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Conjunctival haemorrhage		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dacryoadenitis acquired		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dacryostenosis acquired		

subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic glaucoma		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic retinal oedema		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic retinopathy		
subjects affected / exposed	9 / 9539 (0.09%)	18 / 9544 (0.19%)
occurrences causally related to treatment / all	0 / 9	0 / 20
deaths causally related to treatment / all	0 / 0	0 / 0
Diplopia		
subjects affected / exposed	2 / 9539 (0.02%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	1 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Eye haemorrhage		
subjects affected / exposed	1 / 9539 (0.01%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Glaucoma		
subjects affected / exposed	20 / 9539 (0.21%)	19 / 9544 (0.20%)
occurrences causally related to treatment / all	0 / 20	0 / 19
deaths causally related to treatment / all	0 / 0	0 / 0
Glaucomatous optic disc atrophy		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Keratitis		

subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Macular degeneration		
subjects affected / exposed	7 / 9539 (0.07%)	6 / 9544 (0.06%)
occurrences causally related to treatment / all	0 / 8	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Macular fibrosis		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Macular oedema		
subjects affected / exposed	2 / 9539 (0.02%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Normal tension glaucoma		
subjects affected / exposed	2 / 9539 (0.02%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ocular hypertension		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ocular icterus		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Open angle glaucoma		
subjects affected / exposed	3 / 9539 (0.03%)	4 / 9544 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Optic atrophy		

subjects affected / exposed	0 / 9539 (0.00%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Ophthalmoplegia		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Optic ischaemic neuropathy		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Papilloedema		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Periorbital oedema		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Photophobia		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pterygium		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Photopsia		
subjects affected / exposed	28 / 9539 (0.29%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	29 / 31	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Retinal aneurysm		

subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Retinal artery occlusion		
subjects affected / exposed	2 / 9539 (0.02%)	4 / 9544 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Retinal artery thrombosis		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (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	4 / 9539 (0.04%)	6 / 9544 (0.06%)
occurrences causally related to treatment / all	0 / 4	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Retinal haemorrhage		
subjects affected / exposed	10 / 9539 (0.10%)	4 / 9544 (0.04%)
occurrences causally related to treatment / all	0 / 10	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Retinal tear		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Retinal vascular thrombosis		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Retinal vein occlusion		
subjects affected / exposed	1 / 9539 (0.01%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Retinal vein thrombosis		

subjects affected / exposed	2 / 9539 (0.02%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Retinopathy haemorrhagic		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Retinopathy hypertensive		
subjects affected / exposed	1 / 9539 (0.01%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Retinoschisis		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vision blurred		
subjects affected / exposed	13 / 9539 (0.14%)	5 / 9544 (0.05%)
occurrences causally related to treatment / all	11 / 14	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Visual acuity reduced		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Visual impairment		
subjects affected / exposed	3 / 9539 (0.03%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	2 / 3	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Vitreous detachment		
subjects affected / exposed	3 / 9539 (0.03%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vitreous floaters		

subjects affected / exposed	0 / 9539 (0.00%)	2 / 9544 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vitreous haemorrhage			
subjects affected / exposed	8 / 9539 (0.08%)	4 / 9544 (0.04%)	
occurrences causally related to treatment / all	0 / 10	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal adhesions			
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal discomfort			
subjects affected / exposed	2 / 9539 (0.02%)	2 / 9544 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal distension			
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal hernia			
subjects affected / exposed	2 / 9539 (0.02%)	2 / 9544 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal hernia obstructive			
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain			
subjects affected / exposed	6 / 9539 (0.06%)	7 / 9544 (0.07%)	
occurrences causally related to treatment / all	0 / 6	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain upper			

subjects affected / exposed	4 / 9539 (0.04%)	8 / 9544 (0.08%)
occurrences causally related to treatment / all	0 / 4	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal rigidity		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal strangulated hernia		
subjects affected / exposed	2 / 9539 (0.02%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Acquired oesophageal web		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Acute abdomen		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Anal fissure		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Anal fistula		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Anal polyp		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Anal ulcer		

subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (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	3 / 9539 (0.03%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Barrett's oesophagus		
subjects affected / exposed	2 / 9539 (0.02%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Colitis		
subjects affected / exposed	2 / 9539 (0.02%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Colitis ischaemic		
subjects affected / exposed	2 / 9539 (0.02%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Colitis ulcerative		
subjects affected / exposed	3 / 9539 (0.03%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Colonic pseudo-obstruction		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Colonic stenosis		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Constipation		

subjects affected / exposed	4 / 9539 (0.04%)	5 / 9544 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Crohn's disease		
subjects affected / exposed	1 / 9539 (0.01%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Dental alveolar anomaly		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic gastroparesis		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diaphragmatic hernia		
subjects affected / exposed	0 / 9539 (0.00%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Diarrhoea		
subjects affected / exposed	10 / 9539 (0.10%)	9 / 9544 (0.09%)
occurrences causally related to treatment / all	1 / 10	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Diarrhoea haemorrhagic		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticular perforation		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulitis intestinal haemorrhagic		

subjects affected / exposed	2 / 9539 (0.02%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulum		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulum intestinal		
subjects affected / exposed	3 / 9539 (0.03%)	4 / 9544 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Dry mouth		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulum intestinal haemorrhagic		
subjects affected / exposed	3 / 9539 (0.03%)	6 / 9544 (0.06%)
occurrences causally related to treatment / all	0 / 4	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenal obstruction		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Duodenal polyp		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
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	4 / 9539 (0.04%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenal ulcer haemorrhage		

subjects affected / exposed	7 / 9539 (0.07%)	11 / 9544 (0.12%)
occurrences causally related to treatment / all	0 / 7	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenal ulcer perforation		
subjects affected / exposed	2 / 9539 (0.02%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenitis haemorrhagic		
subjects affected / exposed	2 / 9539 (0.02%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenitis		
subjects affected / exposed	0 / 9539 (0.00%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Dyspepsia		
subjects affected / exposed	4 / 9539 (0.04%)	5 / 9544 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Dysphagia		
subjects affected / exposed	1 / 9539 (0.01%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Enteritis		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Enterocolitis		
subjects affected / exposed	0 / 9539 (0.00%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Enterocolitis haemorrhagic		

subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Epigastric discomfort		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Erosive duodenitis		
subjects affected / exposed	2 / 9539 (0.02%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Erosive oesophagitis		
subjects affected / exposed	3 / 9539 (0.03%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Faecal incontinence		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Flatulence		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Food poisoning		
subjects affected / exposed	3 / 9539 (0.03%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Functional gastrointestinal disorder		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
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	0 / 9539 (0.00%)	4 / 9544 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 1
Gastric mucosa erythema		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric polyps		
subjects affected / exposed	2 / 9539 (0.02%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric ulcer		
subjects affected / exposed	8 / 9539 (0.08%)	8 / 9544 (0.08%)
occurrences causally related to treatment / all	0 / 8	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric ulcer haemorrhage		
subjects affected / exposed	10 / 9539 (0.10%)	15 / 9544 (0.16%)
occurrences causally related to treatment / all	0 / 12	0 / 16
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric ulcer perforation		
subjects affected / exposed	2 / 9539 (0.02%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Gastric varices		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric varices haemorrhage		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastritis		

subjects affected / exposed	14 / 9539 (0.15%)	13 / 9544 (0.14%)
occurrences causally related to treatment / all	0 / 14	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0
Gastritis atrophic		
subjects affected / exposed	5 / 9539 (0.05%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Gastritis erosive		
subjects affected / exposed	10 / 9539 (0.10%)	10 / 9544 (0.10%)
occurrences causally related to treatment / all	0 / 10	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Gastritis haemorrhagic		
subjects affected / exposed	5 / 9539 (0.05%)	7 / 9544 (0.07%)
occurrences causally related to treatment / all	0 / 5	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroduodenal haemorrhage		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroduodenitis		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroduodenitis haemorrhagic		
subjects affected / exposed	0 / 9539 (0.00%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal angiodysplasia		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal angiodysplasia haemorrhagic		

subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal dysplasia		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal erosion		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal haemorrhage		
subjects affected / exposed	13 / 9539 (0.14%)	11 / 9544 (0.12%)
occurrences causally related to treatment / all	0 / 13	0 / 11
deaths causally related to treatment / all	0 / 1	0 / 1
Gastrooesophageal reflux disease		
subjects affected / exposed	12 / 9539 (0.13%)	9 / 9544 (0.09%)
occurrences causally related to treatment / all	0 / 12	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrooesophagitis		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Haematemesis		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haematochezia		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhagic erosive gastritis		

subjects affected / exposed	7 / 9539 (0.07%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 7	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhoidal haemorrhage		
subjects affected / exposed	4 / 9539 (0.04%)	7 / 9544 (0.07%)
occurrences causally related to treatment / all	0 / 4	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhoids		
subjects affected / exposed	0 / 9539 (0.00%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Hernial eventration		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hiatus hernia		
subjects affected / exposed	7 / 9539 (0.07%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 7	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ileal stenosis		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ileus		
subjects affected / exposed	3 / 9539 (0.03%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Ileus paralytic		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Impaired gastric emptying		

subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
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	29 / 9539 (0.30%)	18 / 9544 (0.19%)
occurrences causally related to treatment / all	0 / 31	0 / 18
deaths causally related to treatment / all	0 / 0	0 / 0
Inguinal hernia strangulated		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Inguinal hernia, obstructive		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal angina		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal fistula		
subjects affected / exposed	0 / 9539 (0.00%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal haemorrhage		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal ischaemia		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal mass		

subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal obstruction		
subjects affected / exposed	5 / 9539 (0.05%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal polyp		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal polyp haemorrhage		
subjects affected / exposed	1 / 9539 (0.01%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Irritable bowel syndrome		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Large intestinal haemorrhage		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Large intestine perforation		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Large intestine polyp		
subjects affected / exposed	11 / 9539 (0.12%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	0 / 11	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Leukoplakia oral		

subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lip swelling		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lower gastrointestinal haemorrhage		
subjects affected / exposed	5 / 9539 (0.05%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Mallory-Weiss syndrome		
subjects affected / exposed	1 / 9539 (0.01%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Mechanical ileus		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Melaena		
subjects affected / exposed	6 / 9539 (0.06%)	4 / 9544 (0.04%)
occurrences causally related to treatment / all	0 / 6	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Mesenteric artery thrombosis		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Mesenteric haemorrhage		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Mesenteric occlusion		

subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Mikulicz's disease		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nausea		
subjects affected / exposed	12 / 9539 (0.13%)	8 / 9544 (0.08%)
occurrences causally related to treatment / all	0 / 12	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Oedematous pancreatitis		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal achalasia		
subjects affected / exposed	1 / 9539 (0.01%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal stenosis		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal ulcer haemorrhage		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal varices haemorrhage		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophagitis		

subjects affected / exposed	2 / 9539 (0.02%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophagitis haemorrhagic		
subjects affected / exposed	2 / 9539 (0.02%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophagitis ulcerative		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oral submucosal fibrosis		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatic pseudocyst		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatitis		
subjects affected / exposed	4 / 9539 (0.04%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatitis acute		
subjects affected / exposed	9 / 9539 (0.09%)	17 / 9544 (0.18%)
occurrences causally related to treatment / all	1 / 9	0 / 19
deaths causally related to treatment / all	0 / 0	0 / 1
Pancreatitis chronic		
subjects affected / exposed	11 / 9539 (0.12%)	7 / 9544 (0.07%)
occurrences causally related to treatment / all	0 / 11	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Peptic ulcer		

subjects affected / exposed	1 / 9539 (0.01%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Peptic ulcer haemorrhage		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Periproctitis		
subjects affected / exposed	2 / 9539 (0.02%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Proctitis ulcerative		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal haemorrhage		
subjects affected / exposed	5 / 9539 (0.05%)	8 / 9544 (0.08%)
occurrences causally related to treatment / all	0 / 5	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal polyp		
subjects affected / exposed	3 / 9539 (0.03%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal prolapse		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal ulcer haemorrhage		
subjects affected / exposed	3 / 9539 (0.03%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Reflux gastritis		

subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Retching		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Retroperitoneal haemorrhage		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Salivary gland calculus		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sigmoiditis		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
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	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Small intestinal perforation		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Splenic artery aneurysm		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Subileus		

subjects affected / exposed	3 / 9539 (0.03%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Swollen tongue		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Thrombosis mesenteric vessel		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Tongue ulceration		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Umbilical hernia		
subjects affected / exposed	4 / 9539 (0.04%)	6 / 9544 (0.06%)
occurrences causally related to treatment / all	0 / 4	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Umbilical hernia, obstructive		
subjects affected / exposed	2 / 9539 (0.02%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Upper gastrointestinal haemorrhage		
subjects affected / exposed	8 / 9539 (0.08%)	7 / 9544 (0.07%)
occurrences causally related to treatment / all	0 / 8	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Varices oesophageal		
subjects affected / exposed	4 / 9539 (0.04%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Volvulus		

subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	9 / 9539 (0.09%)	11 / 9544 (0.12%)	
occurrences causally related to treatment / all	1 / 9	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Angioedema			
subjects affected / exposed	4 / 9539 (0.04%)	7 / 9544 (0.07%)	
occurrences causally related to treatment / all	0 / 4	3 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cold sweat			
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Decubitus ulcer			
subjects affected / exposed	2 / 9539 (0.02%)	0 / 9544 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermatitis			
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermatitis allergic			
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermatitis bullous			
subjects affected / exposed	2 / 9539 (0.02%)	0 / 9544 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermatomyositis			

subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic foot		
subjects affected / exposed	4 / 9539 (0.04%)	9 / 9544 (0.09%)
occurrences causally related to treatment / all	0 / 4	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Dry gangrene		
subjects affected / exposed	2 / 9539 (0.02%)	4 / 9544 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Ecchymosis		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Eczema		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Erythema		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hidradenitis		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperhidrosis		
subjects affected / exposed	3 / 9539 (0.03%)	5 / 9544 (0.05%)
occurrences causally related to treatment / all	0 / 3	1 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Keloid scar		

subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Leukocytoclastic vasculitis		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lichen planus		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Necrobiosis lipoidica diabetorum		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neuropathic ulcer		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Panniculitis		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Parapsoriasis		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pruritus		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pemphigus		

subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pruritus allergic		
subjects affected / exposed	3 / 9539 (0.03%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Psoriasis		
subjects affected / exposed	3 / 9539 (0.03%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Purpura		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rash generalised		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Skin lesion		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Skin necrosis		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Skin ulcer		
subjects affected / exposed	2 / 9539 (0.02%)	10 / 9544 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Skin ulcer haemorrhage		

subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Swelling face			
subjects affected / exposed	0 / 9539 (0.00%)	2 / 9544 (0.02%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Toxic skin eruption			
subjects affected / exposed	1 / 9539 (0.01%)	2 / 9544 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urticaria			
subjects affected / exposed	0 / 9539 (0.00%)	2 / 9544 (0.02%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute prerenal failure			
subjects affected / exposed	0 / 9539 (0.00%)	2 / 9544 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anuria			
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder dilatation			
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder diverticulum			
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder neck sclerosis			

subjects affected / exposed	0 / 9539 (0.00%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder prolapse		
subjects affected / exposed	0 / 9539 (0.00%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder perforation		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder stenosis		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder tamponade		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Calculus bladder		
subjects affected / exposed	2 / 9539 (0.02%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Calculus ureteric		
subjects affected / exposed	7 / 9539 (0.07%)	6 / 9544 (0.06%)
occurrences causally related to treatment / all	0 / 7	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Calculus urethral		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Calculus urinary		

subjects affected / exposed	10 / 9539 (0.10%)	7 / 9544 (0.07%)
occurrences causally related to treatment / all	0 / 10	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Cystitis glandularis		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cystitis haemorrhagic		
subjects affected / exposed	4 / 9539 (0.04%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cystitis noninfective		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic nephropathy		
subjects affected / exposed	11 / 9539 (0.12%)	7 / 9544 (0.07%)
occurrences causally related to treatment / all	0 / 12	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Dysuria		
subjects affected / exposed	3 / 9539 (0.03%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Glomerulonephritis		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haematuria		
subjects affected / exposed	6 / 9539 (0.06%)	6 / 9544 (0.06%)
occurrences causally related to treatment / all	0 / 6	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Hydronephrosis		

subjects affected / exposed	6 / 9539 (0.06%)	5 / 9544 (0.05%)
occurrences causally related to treatment / all	0 / 6	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Hydroureter		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertensive nephropathy		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertonic bladder		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
IgA nephropathy		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (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 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Nephroangiosclerosis		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Nephrolithiasis		
subjects affected / exposed	7 / 9539 (0.07%)	14 / 9544 (0.15%)
occurrences causally related to treatment / all	0 / 7	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0
Nephropathy		

subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nephropathy toxic		
subjects affected / exposed	0 / 9539 (0.00%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Nephrotic syndrome		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Obstructive uropathy		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pollakiuria		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Prerenal failure		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal artery occlusion		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renal artery stenosis		
subjects affected / exposed	6 / 9539 (0.06%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	0 / 6	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Renal artery thrombosis		

subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal colic		
subjects affected / exposed	3 / 9539 (0.03%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Renal cyst		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
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	38 / 9539 (0.40%)	30 / 9544 (0.31%)
occurrences causally related to treatment / all	1 / 39	0 / 30
deaths causally related to treatment / all	0 / 0	0 / 3
Renal failure acute		
subjects affected / exposed	29 / 9539 (0.30%)	35 / 9544 (0.37%)
occurrences causally related to treatment / all	0 / 31	0 / 38
deaths causally related to treatment / all	0 / 0	0 / 1
Renal failure chronic		
subjects affected / exposed	34 / 9539 (0.36%)	17 / 9544 (0.18%)
occurrences causally related to treatment / all	1 / 35	0 / 17
deaths causally related to treatment / all	0 / 1	0 / 0
Renal impairment		
subjects affected / exposed	13 / 9539 (0.14%)	5 / 9544 (0.05%)
occurrences causally related to treatment / all	0 / 14	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Renal infarct		
subjects affected / exposed	0 / 9539 (0.00%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Renal ischaemia		

subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal tubular acidosis		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Stress urinary incontinence		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tubulointerstitial nephritis		
subjects affected / exposed	2 / 9539 (0.02%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ureteric obstruction		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ureteric stenosis		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Urethral disorder		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Urethral obstruction		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Urethral stenosis		

subjects affected / exposed	3 / 9539 (0.03%)	6 / 9544 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary bladder haemorrhage			
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary bladder polyp			
subjects affected / exposed	0 / 9539 (0.00%)	3 / 9544 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary incontinence			
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary retention			
subjects affected / exposed	12 / 9539 (0.13%)	18 / 9544 (0.19%)	
occurrences causally related to treatment / all	0 / 14	0 / 18	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract obstruction			
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vesicoureteric reflux			
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Autoimmune thyroiditis			
subjects affected / exposed	2 / 9539 (0.02%)	3 / 9544 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adrenal insufficiency			

subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Basedow's disease		
subjects affected / exposed	2 / 9539 (0.02%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cushing's syndrome		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Empty sella syndrome		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Goitre		
subjects affected / exposed	4 / 9539 (0.04%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperthyroidism		
subjects affected / exposed	6 / 9539 (0.06%)	5 / 9544 (0.05%)
occurrences causally related to treatment / all	0 / 7	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Hypothyroidism		
subjects affected / exposed	2 / 9539 (0.02%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Inappropriate antidiuretic hormone secretion		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Toxic nodular goitre		

subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Amyotrophy			
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ankylosing spondylitis			
subjects affected / exposed	2 / 9539 (0.02%)	0 / 9544 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthralgia			
subjects affected / exposed	1 / 9539 (0.01%)	3 / 9544 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis			
subjects affected / exposed	1 / 9539 (0.01%)	3 / 9544 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bursitis			
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Back pain			
subjects affected / exposed	7 / 9539 (0.07%)	7 / 9544 (0.07%)	
occurrences causally related to treatment / all	0 / 7	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
CREST syndrome			
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical spinal stenosis			

subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Chondrocalcinosis pyrophosphate		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Chondromalacia		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Chondropathy		
subjects affected / exposed	0 / 9539 (0.00%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Costochondritis		
subjects affected / exposed	3 / 9539 (0.03%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dupuytren's contracture		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Exostosis		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Exostosis of jaw		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Fasciitis		

subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Fistula		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Foot deformity		
subjects affected / exposed	2 / 9539 (0.02%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gouty arthritis		
subjects affected / exposed	1 / 9539 (0.01%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	0 / 1	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Gouty tophus		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Groin pain		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haemarthrosis		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral disc compression		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral disc degeneration		

subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral disc disorder		
subjects affected / exposed	4 / 9539 (0.04%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	0 / 6	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral disc displacement		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral disc protrusion		
subjects affected / exposed	12 / 9539 (0.13%)	20 / 9544 (0.21%)
occurrences causally related to treatment / all	0 / 12	0 / 20
deaths causally related to treatment / all	0 / 0	0 / 0
Kyphosis		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lumbar spinal stenosis		
subjects affected / exposed	9 / 9539 (0.09%)	8 / 9544 (0.08%)
occurrences causally related to treatment / all	0 / 9	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Mobility decreased		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Muscle haemorrhage		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Muscle tightness		

subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Muscular weakness		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Musculoskeletal chest pain		
subjects affected / exposed	3 / 9539 (0.03%)	11 / 9544 (0.12%)
occurrences causally related to treatment / all	0 / 3	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Musculoskeletal pain		
subjects affected / exposed	3 / 9539 (0.03%)	6 / 9544 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Musculoskeletal stiffness		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Myopathy		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Myopathy toxic		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neck pain		
subjects affected / exposed	1 / 9539 (0.01%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Neuropathic arthropathy		

subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Osteitis		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Osteoarthritis		
subjects affected / exposed	46 / 9539 (0.48%)	43 / 9544 (0.45%)
occurrences causally related to treatment / all	0 / 47	0 / 48
deaths causally related to treatment / all	0 / 0	0 / 0
Osteochondritis		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Osteochondrosis		
subjects affected / exposed	1 / 9539 (0.01%)	8 / 9544 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Osteonecrosis		
subjects affected / exposed	5 / 9539 (0.05%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Osteoporosis		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Osteoporosis postmenopausal		
subjects affected / exposed	1 / 9539 (0.01%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Osteoporotic fracture		

subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pain in extremity		
subjects affected / exposed	4 / 9539 (0.04%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Patellofemoral pain syndrome		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Periarthritis		
subjects affected / exposed	1 / 9539 (0.01%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Polymyalgia rheumatica		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pseudarthrosis		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Psoriatic arthropathy		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rhabdomyolysis		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rheumatoid arthritis		

subjects affected / exposed	2 / 9539 (0.02%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Rotator cuff syndrome		
subjects affected / exposed	4 / 9539 (0.04%)	5 / 9544 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Scoliosis		
subjects affected / exposed	2 / 9539 (0.02%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal column stenosis		
subjects affected / exposed	3 / 9539 (0.03%)	10 / 9544 (0.10%)
occurrences causally related to treatment / all	0 / 3	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal osteoarthritis		
subjects affected / exposed	18 / 9539 (0.19%)	16 / 9544 (0.17%)
occurrences causally related to treatment / all	0 / 18	0 / 18
deaths causally related to treatment / all	0 / 0	0 / 0
Spondyloarthropathy		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Spondylolisthesis		
subjects affected / exposed	2 / 9539 (0.02%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Sympathetic posterior cervical syndrome		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Synovitis		

subjects affected / exposed	3 / 9539 (0.03%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Systemic sclerosis			
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tenosynovitis			
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebral foraminal stenosis			
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (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 wall abscess			
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess jaw			
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)	
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 / 9539 (0.01%)	2 / 9544 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute hepatitis C			
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute sinusitis			

subjects affected / exposed	1 / 9539 (0.01%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Anal abscess		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Anal candidiasis		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Appendiceal abscess		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Appendicitis		
subjects affected / exposed	16 / 9539 (0.17%)	9 / 9544 (0.09%)
occurrences causally related to treatment / all	0 / 18	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Appendicitis perforated		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Arteriosclerotic gangrene		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Arteriovenous graft site infection		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Arthritis bacterial		

subjects affected / exposed	0 / 9539 (0.00%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Atypical pneumonia		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bacteraemia		
subjects affected / exposed	3 / 9539 (0.03%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bacterial diarrhoea		
subjects affected / exposed	0 / 9539 (0.00%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Bacterial infection		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bacterial prostatitis		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bacterial sepsis		
subjects affected / exposed	2 / 9539 (0.02%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
Biliary tract infection		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Borrelia infection		

subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Brain abscess		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchiolitis		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchitis		
subjects affected / exposed	16 / 9539 (0.17%)	22 / 9544 (0.23%)
occurrences causally related to treatment / all	0 / 16	0 / 28
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchopneumonia		
subjects affected / exposed	29 / 9539 (0.30%)	24 / 9544 (0.25%)
occurrences causally related to treatment / all	0 / 33	0 / 26
deaths causally related to treatment / all	0 / 1	0 / 2
Bronchitis bacterial		
subjects affected / exposed	4 / 9539 (0.04%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchopulmonary aspergillosis		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Campylobacter gastroenteritis		
subjects affected / exposed	3 / 9539 (0.03%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Candida pneumonia		

subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Candidiasis		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Carbuncle		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cellulitis		
subjects affected / exposed	23 / 9539 (0.24%)	18 / 9544 (0.19%)
occurrences causally related to treatment / all	0 / 23	0 / 19
deaths causally related to treatment / all	0 / 0	0 / 0
Cellulitis gangrenous		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cervicitis		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cholangitis suppurative		
subjects affected / exposed	0 / 9539 (0.00%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cholecystitis infective		
subjects affected / exposed	5 / 9539 (0.05%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic hepatitis C		

subjects affected / exposed	1 / 9539 (0.01%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic sinusitis		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cystitis		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Clostridium difficile colitis		
subjects affected / exposed	4 / 9539 (0.04%)	4 / 9544 (0.04%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 0
Cystitis klebsiella		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dengue fever		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Device related infection		
subjects affected / exposed	1 / 9539 (0.01%)	4 / 9544 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic foot infection		
subjects affected / exposed	5 / 9539 (0.05%)	8 / 9544 (0.08%)
occurrences causally related to treatment / all	0 / 6	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic gangrene		

subjects affected / exposed	4 / 9539 (0.04%)	13 / 9544 (0.14%)
occurrences causally related to treatment / all	0 / 4	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0
Diarrhoea infectious		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulitis		
subjects affected / exposed	5 / 9539 (0.05%)	8 / 9544 (0.08%)
occurrences causally related to treatment / all	0 / 5	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Ear infection		
subjects affected / exposed	2 / 9539 (0.02%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Echinococcosis		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Emphysematous cholecystitis		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Empyema		
subjects affected / exposed	2 / 9539 (0.02%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Endocarditis		
subjects affected / exposed	2 / 9539 (0.02%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Endocarditis bacterial		

subjects affected / exposed	2 / 9539 (0.02%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0
Endocarditis enterococcal		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Endocarditis staphylococcal		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Enterobacter sepsis		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Enterococcal sepsis		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Enterocolitis bacterial		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Enterocolitis infectious		
subjects affected / exposed	0 / 9539 (0.00%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Epiglottitis		
subjects affected / exposed	0 / 9539 (0.00%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Erysipelas		

subjects affected / exposed	20 / 9539 (0.21%)	15 / 9544 (0.16%)
occurrences causally related to treatment / all	0 / 20	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0
Escherichia infection		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
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 / 9539 (0.02%)	7 / 9544 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Folliculitis		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gallbladder empyema		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gangrene		
subjects affected / exposed	7 / 9539 (0.07%)	5 / 9544 (0.05%)
occurrences causally related to treatment / all	0 / 9	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 0
Gastroenteritis		
subjects affected / exposed	16 / 9539 (0.17%)	16 / 9544 (0.17%)
occurrences causally related to treatment / all	0 / 16	0 / 16
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis bacterial		
subjects affected / exposed	0 / 9539 (0.00%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis clostridial		

subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis salmonella		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis shigella		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis viral		
subjects affected / exposed	0 / 9539 (0.00%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal bacterial infection		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal viral infection		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
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	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Haemophilus infection		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Helicobacter gastritis		

subjects affected / exposed	2 / 9539 (0.02%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Helicobacter infection		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
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	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatitis B		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatitis C		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Herpes zoster		
subjects affected / exposed	1 / 9539 (0.01%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Herpes zoster infection neurological		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Herpes zoster ophthalmic		
subjects affected / exposed	2 / 9539 (0.02%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Herpes zoster oticus		

subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Infected cyst		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (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	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Infected skin ulcer		
subjects affected / exposed	0 / 9539 (0.00%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Infection		
subjects affected / exposed	0 / 9539 (0.00%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Infectious pleural effusion		
subjects affected / exposed	1 / 9539 (0.01%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Infective exacerbation of bronchiectasis		
subjects affected / exposed	3 / 9539 (0.03%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Infective exacerbation of chronic obstructive airways disease		
subjects affected / exposed	5 / 9539 (0.05%)	6 / 9544 (0.06%)
occurrences causally related to treatment / all	0 / 5	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Infective myositis		

subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Influenza		
subjects affected / exposed	3 / 9539 (0.03%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Injection site abscess		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral discitis		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Joint abscess		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Keratitis herpetic		
subjects affected / exposed	2 / 9539 (0.02%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Laryngitis		
subjects affected / exposed	2 / 9539 (0.02%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Laryngitis bacterial		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Laryngitis fungal		

subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Legionella infection		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Liver abscess		
subjects affected / exposed	3 / 9539 (0.03%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lobar pneumonia		
subjects affected / exposed	6 / 9539 (0.06%)	13 / 9544 (0.14%)
occurrences causally related to treatment / all	0 / 6	0 / 13
deaths causally related to treatment / all	0 / 1	0 / 0
Localised infection		
subjects affected / exposed	0 / 9539 (0.00%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Lower respiratory tract infection		
subjects affected / exposed	5 / 9539 (0.05%)	9 / 9544 (0.09%)
occurrences causally related to treatment / all	0 / 5	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Lower respiratory tract infection bacterial		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lung abscess		
subjects affected / exposed	4 / 9539 (0.04%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lung infection		

subjects affected / exposed	11 / 9539 (0.12%)	8 / 9544 (0.08%)
occurrences causally related to treatment / all	0 / 11	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Lyme disease		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphangitis		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Malaria		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Mastoiditis		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Mediastinal abscess		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Mediastinitis		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Meningitis		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Meningitis tuberculous		

subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Meningitis viral		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Muscle abscess		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Necrotising fasciitis		
subjects affected / exposed	0 / 9539 (0.00%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal candidiasis		
subjects affected / exposed	0 / 9539 (0.00%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Orchitis		
subjects affected / exposed	2 / 9539 (0.02%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Osteomyelitis		
subjects affected / exposed	2 / 9539 (0.02%)	11 / 9544 (0.12%)
occurrences causally related to treatment / all	0 / 2	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Osteomyelitis bacterial		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Osteomyelitis chronic		

subjects affected / exposed	0 / 9539 (0.00%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Otitis media		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Otitis media acute		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Otitis media chronic		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pelvic abscess		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Perihepatic abscess		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Perineal abscess		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Periodontitis		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peritoneal abscess		

subjects affected / exposed	2 / 9539 (0.02%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peritonitis		
subjects affected / exposed	9 / 9539 (0.09%)	9 / 9544 (0.09%)
occurrences causally related to treatment / all	0 / 9	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 2
Peritonitis bacterial		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peritonsillar abscess		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pertussis		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pharyngitis		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (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 / 9539 (0.01%)	0 / 9544 (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	122 / 9539 (1.28%)	102 / 9544 (1.07%)
occurrences causally related to treatment / all	0 / 129	0 / 112
deaths causally related to treatment / all	0 / 6	0 / 3
Pneumonia bacterial		

subjects affected / exposed	7 / 9539 (0.07%)	7 / 9544 (0.07%)
occurrences causally related to treatment / all	0 / 8	0 / 7
deaths causally related to treatment / all	0 / 1	0 / 0
Pneumonia escherichia		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia haemophilus		
subjects affected / exposed	1 / 9539 (0.01%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia klebsiella		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia moraxella		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia mycoplasmal		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (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 / 9539 (0.01%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia pseudomonas aeruginosa		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia streptococcal		

subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia viral		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural cellulitis		
subjects affected / exposed	0 / 9539 (0.00%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural infection		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Post procedural sepsis		
subjects affected / exposed	1 / 9539 (0.01%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative abscess		
subjects affected / exposed	0 / 9539 (0.00%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative wound infection		
subjects affected / exposed	6 / 9539 (0.06%)	12 / 9544 (0.13%)
occurrences causally related to treatment / all	0 / 6	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0
Pseudomembranous colitis		
subjects affected / exposed	0 / 9539 (0.00%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pseudomonal bacteraemia		

subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary sepsis		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary tuberculoma		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary tuberculosis		
subjects affected / exposed	4 / 9539 (0.04%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Puncture site abscess		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Puncture site infection		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pyelonephritis		
subjects affected / exposed	3 / 9539 (0.03%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pyelonephritis acute		
subjects affected / exposed	5 / 9539 (0.05%)	8 / 9544 (0.08%)
occurrences causally related to treatment / all	0 / 5	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Pyelonephritis chronic		

subjects affected / exposed	7 / 9539 (0.07%)	6 / 9544 (0.06%)
occurrences causally related to treatment / all	0 / 7	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Pyoderma		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pyonephrosis		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal tuberculosis		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory syncytial virus infection		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory moniliasis		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory tract infection		
subjects affected / exposed	5 / 9539 (0.05%)	12 / 9544 (0.13%)
occurrences causally related to treatment / all	0 / 5	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory tract infection bacterial		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory tract infection viral		

subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Salmonellosis		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sepsis		
subjects affected / exposed	11 / 9539 (0.12%)	11 / 9544 (0.12%)
occurrences causally related to treatment / all	0 / 11	0 / 11
deaths causally related to treatment / all	0 / 5	0 / 3
Scrotal abscess		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Septic arthritis staphylococcal		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Septic shock		
subjects affected / exposed	9 / 9539 (0.09%)	13 / 9544 (0.14%)
occurrences causally related to treatment / all	0 / 9	0 / 13
deaths causally related to treatment / all	0 / 6	0 / 5
Sinusitis		
subjects affected / exposed	0 / 9539 (0.00%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Skin infection		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Small intestine gangrene		

subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Sputum purulent		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (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	2 / 9539 (0.02%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Staphylococcal osteomyelitis		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Staphylococcal sepsis		
subjects affected / exposed	2 / 9539 (0.02%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Streptococcal sepsis		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
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	4 / 9539 (0.04%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Systemic candida		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tonsillitis bacterial		

subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tooth infection		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Toxic shock syndrome		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tracheobronchitis		
subjects affected / exposed	3 / 9539 (0.03%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tuberculosis gastrointestinal		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (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	2 / 9539 (0.02%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tubo-ovarian abscess		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Typhoid fever		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Upper respiratory tract infection		

subjects affected / exposed	6 / 9539 (0.06%)	4 / 9544 (0.04%)
occurrences causally related to treatment / all	0 / 6	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary tract infection		
subjects affected / exposed	26 / 9539 (0.27%)	17 / 9544 (0.18%)
occurrences causally related to treatment / all	0 / 26	0 / 18
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary tract infection bacterial		
subjects affected / exposed	7 / 9539 (0.07%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	0 / 7	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary tract infection enterococcal		
subjects affected / exposed	2 / 9539 (0.02%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Urosepsis		
subjects affected / exposed	4 / 9539 (0.04%)	13 / 9544 (0.14%)
occurrences causally related to treatment / all	0 / 4	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 1
Viral infection		
subjects affected / exposed	3 / 9539 (0.03%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Viral pericarditis		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Wound infection		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Wound infection bacterial		

subjects affected / exposed	3 / 9539 (0.03%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound infection pseudomonas			
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Acidosis			
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cachexia			
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Decreased appetite			
subjects affected / exposed	4 / 9539 (0.04%)	3 / 9544 (0.03%)	
occurrences causally related to treatment / all	1 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dehydration			
subjects affected / exposed	19 / 9539 (0.20%)	19 / 9544 (0.20%)	
occurrences causally related to treatment / all	0 / 20	0 / 19	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetes mellitus			
subjects affected / exposed	59 / 9539 (0.62%)	82 / 9544 (0.86%)	
occurrences causally related to treatment / all	0 / 65	0 / 87	
deaths causally related to treatment / all	0 / 0	0 / 1	
Diabetes mellitus inadequate control			
subjects affected / exposed	34 / 9539 (0.36%)	50 / 9544 (0.52%)	
occurrences causally related to treatment / all	0 / 36	0 / 53	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic complication			

subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic ketoacidosis		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Fluid retention		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gout		
subjects affected / exposed	4 / 9539 (0.04%)	3 / 9544 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Hypercholesterolaemia		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperglycaemia		
subjects affected / exposed	10 / 9539 (0.10%)	4 / 9544 (0.04%)
occurrences causally related to treatment / all	0 / 11	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperkalaemia		
subjects affected / exposed	13 / 9539 (0.14%)	10 / 9544 (0.10%)
occurrences causally related to treatment / all	0 / 14	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertriglyceridaemia		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypocalcaemia		

subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (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	19 / 9539 (0.20%)	12 / 9544 (0.13%)
occurrences causally related to treatment / all	0 / 20	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0
Hypokalaemia		
subjects affected / exposed	4 / 9539 (0.04%)	5 / 9544 (0.05%)
occurrences causally related to treatment / all	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Hypomagnesaemia		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hyponatraemia		
subjects affected / exposed	1 / 9539 (0.01%)	7 / 9544 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoproteinaemia		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Insulin-requiring type 2 diabetes mellitus		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ketoacidosis		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lactic acidosis		

subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Malnutrition		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Metabolic acidosis		
subjects affected / exposed	1 / 9539 (0.01%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Metabolic alkalosis		
subjects affected / exposed	0 / 9539 (0.00%)	2 / 9544 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Obesity		
subjects affected / exposed	0 / 9539 (0.00%)	1 / 9544 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Type 1 diabetes mellitus		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Type 2 diabetes mellitus		
subjects affected / exposed	25 / 9539 (0.26%)	47 / 9544 (0.49%)
occurrences causally related to treatment / all	0 / 26	0 / 52
deaths causally related to treatment / all	0 / 0	0 / 0
Type 3 diabetes mellitus		
subjects affected / exposed	1 / 9539 (0.01%)	0 / 9544 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0

Frequency threshold for reporting non-serious adverse events: 1 %

Non-serious adverse events	Ivabradine	Placebo	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6920 / 9539 (72.54%)	6321 / 9544 (66.23%)	
Vascular disorders			
Hypertensive crisis			
subjects affected / exposed	129 / 9539 (1.35%)	140 / 9544 (1.47%)	
occurrences (all)	147	160	
Hypertension			
subjects affected / exposed	1129 / 9539 (11.84%)	923 / 9544 (9.67%)	
occurrences (all)	1322	1070	
Hypotension			
subjects affected / exposed	178 / 9539 (1.87%)	190 / 9544 (1.99%)	
occurrences (all)	187	198	
Peripheral arterial occlusive disease			
subjects affected / exposed	122 / 9539 (1.28%)	128 / 9544 (1.34%)	
occurrences (all)	131	135	
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	108 / 9539 (1.13%)	132 / 9544 (1.38%)	
occurrences (all)	121	158	
Non-cardiac chest pain			
subjects affected / exposed	119 / 9539 (1.25%)	114 / 9544 (1.19%)	
occurrences (all)	131	123	
Fatigue			
subjects affected / exposed	126 / 9539 (1.32%)	110 / 9544 (1.15%)	
occurrences (all)	131	116	
Oedema peripheral			
subjects affected / exposed	214 / 9539 (2.24%)	170 / 9544 (1.78%)	
occurrences (all)	234	178	
Reproductive system and breast disorders			
Benign prostatic hyperplasia			
subjects affected / exposed	121 / 9539 (1.27%)	132 / 9544 (1.38%)	
occurrences (all)	121	132	

Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease			
subjects affected / exposed	168 / 9539 (1.76%)	152 / 9544 (1.59%)	
occurrences (all)	211	198	
Cough			
subjects affected / exposed	154 / 9539 (1.61%)	138 / 9544 (1.45%)	
occurrences (all)	165	146	
Dyspnoea			
subjects affected / exposed	136 / 9539 (1.43%)	114 / 9544 (1.19%)	
occurrences (all)	144	121	
Psychiatric disorders			
Insomnia			
subjects affected / exposed	100 / 9539 (1.05%)	99 / 9544 (1.04%)	
occurrences (all)	102	102	
Investigations			
Blood pressure increased			
subjects affected / exposed	118 / 9539 (1.24%)	117 / 9544 (1.23%)	
occurrences (all)	145	145	
Blood creatinine increased			
subjects affected / exposed	114 / 9539 (1.20%)	88 / 9544 (0.92%)	
occurrences (all)	118	89	
C-reactive protein increased			
subjects affected / exposed	155 / 9539 (1.62%)	140 / 9544 (1.47%)	
occurrences (all)	159	143	
Electrocardiogram QT prolonged			
subjects affected / exposed	161 / 9539 (1.69%)	58 / 9544 (0.61%)	
occurrences (all)	178	62	
Heart rate decreased			
subjects affected / exposed	1032 / 9539 (10.82%)	112 / 9544 (1.17%)	
occurrences (all)	1173	123	
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	259 / 9539 (2.72%)	287 / 9544 (3.01%)	
occurrences (all)	284	313	
Cardiac disorders			

Acute myocardial infarction subjects affected / exposed occurrences (all)	200 / 9539 (2.10%) 216	208 / 9544 (2.18%) 229
Angina pectoris subjects affected / exposed occurrences (all)	611 / 9539 (6.41%) 684	692 / 9544 (7.25%) 774
Angina unstable subjects affected / exposed occurrences (all)	412 / 9539 (4.32%) 482	436 / 9544 (4.57%) 527
Atrioventricular block first degree subjects affected / exposed occurrences (all)	251 / 9539 (2.63%) 269	204 / 9544 (2.14%) 222
Atrial fibrillation subjects affected / exposed occurrences (all)	438 / 9539 (4.59%) 538	316 / 9544 (3.31%) 370
Cardiac failure subjects affected / exposed occurrences (all)	469 / 9539 (4.92%) 546	464 / 9544 (4.86%) 531
Bradycardia subjects affected / exposed occurrences (all)	569 / 9539 (5.96%) 613	77 / 9544 (0.81%) 84
Myocardial infarction subjects affected / exposed occurrences (all)	98 / 9539 (1.03%) 104	83 / 9544 (0.87%) 88
Sinus bradycardia subjects affected / exposed occurrences (all)	189 / 9539 (1.98%) 199	22 / 9544 (0.23%) 24
Sinus tachycardia subjects affected / exposed occurrences (all)	46 / 9539 (0.48%) 46	170 / 9544 (1.78%) 193
Supraventricular extrasystoles subjects affected / exposed occurrences (all)	184 / 9539 (1.93%) 194	143 / 9544 (1.50%) 144
Ventricular extrasystoles subjects affected / exposed occurrences (all)	335 / 9539 (3.51%) 363	264 / 9544 (2.77%) 288

Nervous system disorders			
Dizziness			
subjects affected / exposed	291 / 9539 (3.05%)	217 / 9544 (2.27%)	
occurrences (all)	311	235	
Headache			
subjects affected / exposed	170 / 9539 (1.78%)	146 / 9544 (1.53%)	
occurrences (all)	195	162	
Ischaemic stroke			
subjects affected / exposed	97 / 9539 (1.02%)	90 / 9544 (0.94%)	
occurrences (all)	100	95	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	214 / 9539 (2.24%)	240 / 9544 (2.51%)	
occurrences (all)	221	249	
Eye disorders			
Cataract			
subjects affected / exposed	157 / 9539 (1.65%)	189 / 9544 (1.98%)	
occurrences (all)	175	203	
Photopsia			
subjects affected / exposed	509 / 9539 (5.34%)	51 / 9544 (0.53%)	
occurrences (all)	567	52	
Vision blurred			
subjects affected / exposed	115 / 9539 (1.21%)	36 / 9544 (0.38%)	
occurrences (all)	119	36	
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	99 / 9539 (1.04%)	102 / 9544 (1.07%)	
occurrences (all)	106	107	
Diarrhoea			
subjects affected / exposed	125 / 9539 (1.31%)	121 / 9544 (1.27%)	
occurrences (all)	131	129	
Gastritis			
subjects affected / exposed	108 / 9539 (1.13%)	124 / 9544 (1.30%)	
occurrences (all)	111	127	
Nausea			
subjects affected / exposed	96 / 9539 (1.01%)	83 / 9544 (0.87%)	
occurrences (all)	102	87	

Renal and urinary disorders			
Renal failure			
subjects affected / exposed	112 / 9539 (1.17%)	89 / 9544 (0.93%)	
occurrences (all)	118	90	
Renal failure chronic			
subjects affected / exposed	105 / 9539 (1.10%)	82 / 9544 (0.86%)	
occurrences (all)	109	82	
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	102 / 9539 (1.07%)	115 / 9544 (1.20%)	
occurrences (all)	107	121	
Arthralgia			
subjects affected / exposed	71 / 9539 (0.74%)	98 / 9544 (1.03%)	
occurrences (all)	75	102	
Osteoarthritis			
subjects affected / exposed	148 / 9539 (1.55%)	192 / 9544 (2.01%)	
occurrences (all)	163	209	
Spinal osteoarthritis			
subjects affected / exposed	125 / 9539 (1.31%)	134 / 9544 (1.40%)	
occurrences (all)	131	143	
Infections and infestations			
Bronchitis			
subjects affected / exposed	228 / 9539 (2.39%)	201 / 9544 (2.11%)	
occurrences (all)	257	226	
Influenza			
subjects affected / exposed	116 / 9539 (1.22%)	169 / 9544 (1.77%)	
occurrences (all)	126	177	
Pneumonia			
subjects affected / exposed	170 / 9539 (1.78%)	146 / 9544 (1.53%)	
occurrences (all)	183	161	
Nasopharyngitis			
subjects affected / exposed	172 / 9539 (1.80%)	172 / 9544 (1.80%)	
occurrences (all)	195	198	
Upper respiratory tract infection			
subjects affected / exposed	172 / 9539 (1.80%)	179 / 9544 (1.88%)	
occurrences (all)	200	219	

Urinary tract infection subjects affected / exposed occurrences (all)	129 / 9539 (1.35%) 137	116 / 9544 (1.22%) 136	
Metabolism and nutrition disorders			
Diabetes mellitus subjects affected / exposed occurrences (all)	241 / 9539 (2.53%) 264	320 / 9544 (3.35%) 347	
Diabetes mellitus inadequate control subjects affected / exposed occurrences (all)	109 / 9539 (1.14%) 115	132 / 9544 (1.38%) 141	
Hyperglycaemia subjects affected / exposed occurrences (all)	109 / 9539 (1.14%) 113	103 / 9544 (1.08%) 108	
Hypercholesterolaemia subjects affected / exposed occurrences (all)	155 / 9539 (1.62%) 162	175 / 9544 (1.83%) 184	
Hyperkalaemia subjects affected / exposed occurrences (all)	152 / 9539 (1.59%) 159	121 / 9544 (1.27%) 131	
Type 2 diabetes mellitus subjects affected / exposed occurrences (all)	161 / 9539 (1.69%) 167	217 / 9544 (2.27%) 231	
Hypertriglyceridaemia subjects affected / exposed occurrences (all)	150 / 9539 (1.57%) 154	159 / 9544 (1.67%) 162	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
08 June 2010	<p>Amendment No. 1 was applicable in all countries. The aims were:</p> <ul style="list-style-type: none">- To update the list of secondary efficacy endpoints: a new endpoint "coronary death" (a sub-category of cardiovascular deaths) was added, based on the BEAUTIFUL data, where the benefits of ivabradine had been observed mainly on coronary events;- To clarify the criteria for the documentation of the coronary artery disease (selection criteria). The e-CRF was modified to include more extensive details;- To update the definition of an excessive intake of the study drug and the rules for immediate notification to the sponsor;- To update administrative data (including the list of countries, the names and/or contact details of non-sponsor and sponsor parties), and to update the list of ancillary studies (Biomarkers of coronary artery disease ancillary study was added in selected centres). <p>The amendment did not require any changes to the patient information sheet or informed consent form.</p>
14 June 2011	<p>Amendment No. 2, was applicable in all countries. The aims were:</p> <ul style="list-style-type: none">- To increase the number of patients to be randomised (16 850 instead of 11 330 initially planned) and the extension of the estimated recruitment duration to 30 months (instead of 24 months). These changes were made on the basis of a revised annual incidence in blind for the primary composite endpoint of 2.5% in the overall population (corresponding to 2.7% in the placebo group), with unchanged power (90%), type I error (5%), and relative risk reduction (18%). The planned follow-up duration for the first included patients was extended from 42 months to 48 months.- To update the administrative data (including the list of countries, the names and / or contact details of non-sponsor and sponsor parties).- To clarify the types of source documents needed for the documentation of the CAD in the case of previous coronary revascularisation or presence of significant (> 50%) coronary artery stenosis.- To clarify that patient should receive stable doses of conventional CV medications during the run-in period. <p>This amendment required an amendment to the patient information and consent form. The amended form was to be signed by all patients as soon as the amendment became applicable in their centre: new patients were to sign the complete form, while patients already recruited in the study before the amendment were to sign the short form during their next visit after the amendment implementation.</p>
07 September 2012	<p>Amendment No. 4, was applicable in all countries. The aims were:</p> <ul style="list-style-type: none">- To update information on concomitant treatments to be used with precaution during the study (potassium-depleting diuretics).- To update the list of adverse events for which specific information was requested and already collected (bradycardia, eye disorders, rhythm and conduction disorders, blood pressure increases and QT prolongation).- Additional clarifications and corrections, including definitions of the intensity of adverse events (mild, moderate, and severe).- To update administrative data (Belarus and Saudi Arabia were removed from the list of participating countries). <p>This amendment required an amendment to the patient information and consent form.</p>

30 May 2013	Amendment No. 5 and amendment No. 6 were applicable in all countries where it was permitted to retrieve, for patients who withdrew their study consent, their vital status (amendment No. 5) and the dates of hospitalisations for CV events (amendment No. 6). The aims of these amendments were to minimise the number of patients with missing follow-up information of vital status and hospitalisations for cardiovascular events at the end of the study, while respecting the local regulations. The patients concerned by this procedure were those who withdrew consent from study after the randomisation/inclusion visit and before the start date of the termination visits (scheduled from 1 September to 31 December 2013). In the cases where there was information that a PSE occurred, no PSE file was prepared and the event was not adjudicated by the EVC. Depending on local regulations, these two amendments may or may not have required an amendment to the patient information and consent form.
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Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

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

The section NSAE presented EAEs on treatment and included SEAEs. The causality and seriousness of reported SAE can be ultimately upgraded by the sponsor. The sponsor took these decisions to be compliant with the existing ICH E3 Clinical Study Report.
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Notes: